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Cole

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(54) **SYSTEM AND METHOD FOR LOAD BALANCING IN KNEE REPLACEMENT PROCEDURES**

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Related U.S. Application Data

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(51) **Int. Cl.**

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A61B 17/17	(2006.01)
A61F 2/38	(2006.01)
A61B 17/15	(2006.01)
A61B 17/14	(2006.01)
A61F 2/46	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 17/1764*** (2013.01); ***A61B 17/14*** (2013.01); ***A61B 17/155*** (2013.01); ***A61B 17/1714*** (2013.01); ***A61F 2/0805*** (2013.01); ***A61F 2/3836*** (2013.01); ***A61F 2/4657*** (2013.01); *A61F 2/38* (2013.01); *A61F 2002/087* (2013.01); *A61F 2002/0888* (2013.01); *A61F 2002/4666* (2013.01); *A61F 2250/0003* (2013.01)

(58) **Field of Classification Search**

CPC A61B 2017/565; A61B 17/151; A61B 17/155; A61F 2/3836

See application file for complete search history.

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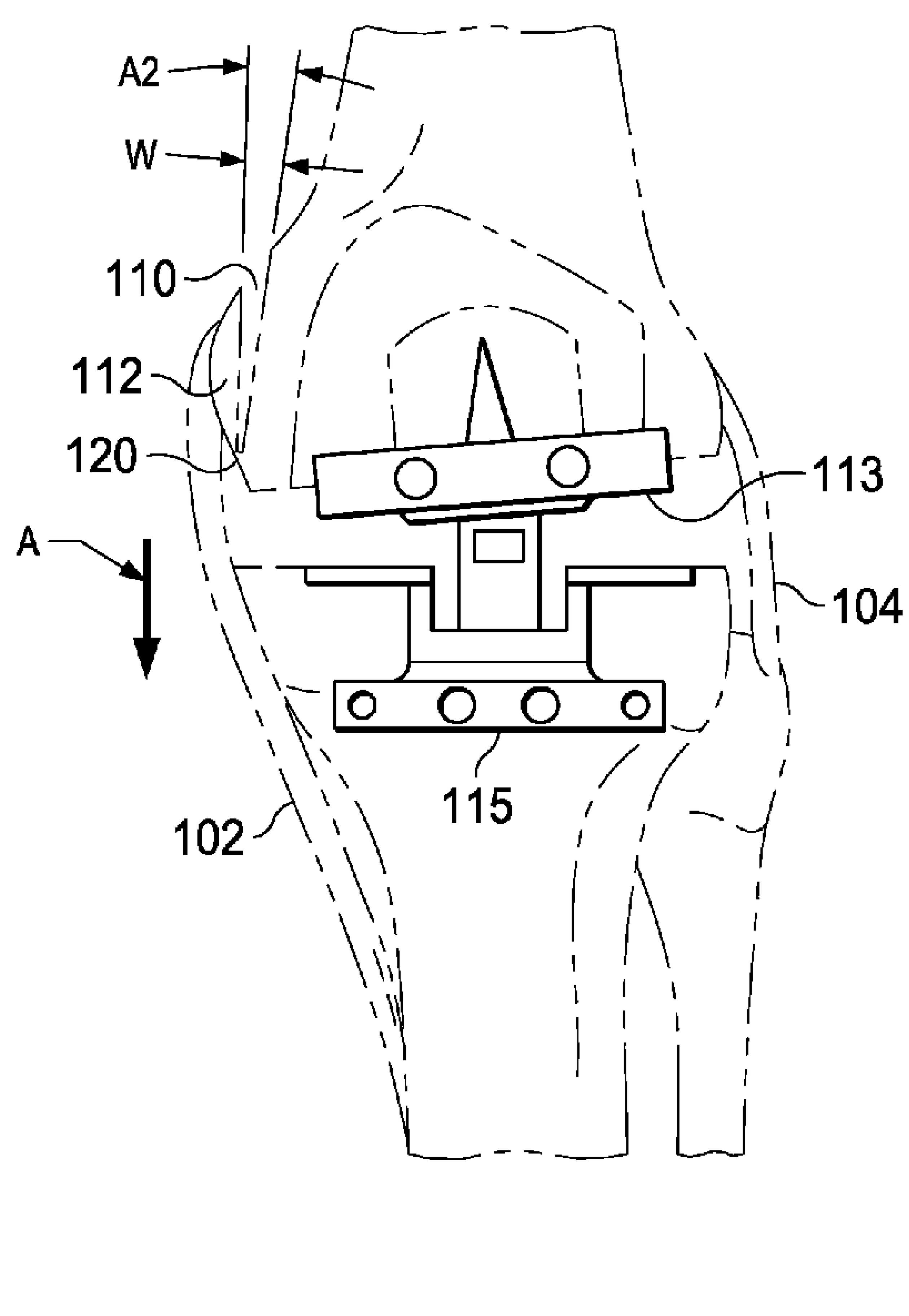
(57) **ABSTRACT**

The present disclosure relates to a system and method of knee ligament balancing for knee replacement procedures. The disclosure provides a system of components to implant to achieve ligament balancing. In addition, instruments and methods are provided to achieve the desired balance of the ligaments before final fixation.

10 Claims, 15 Drawing Sheets



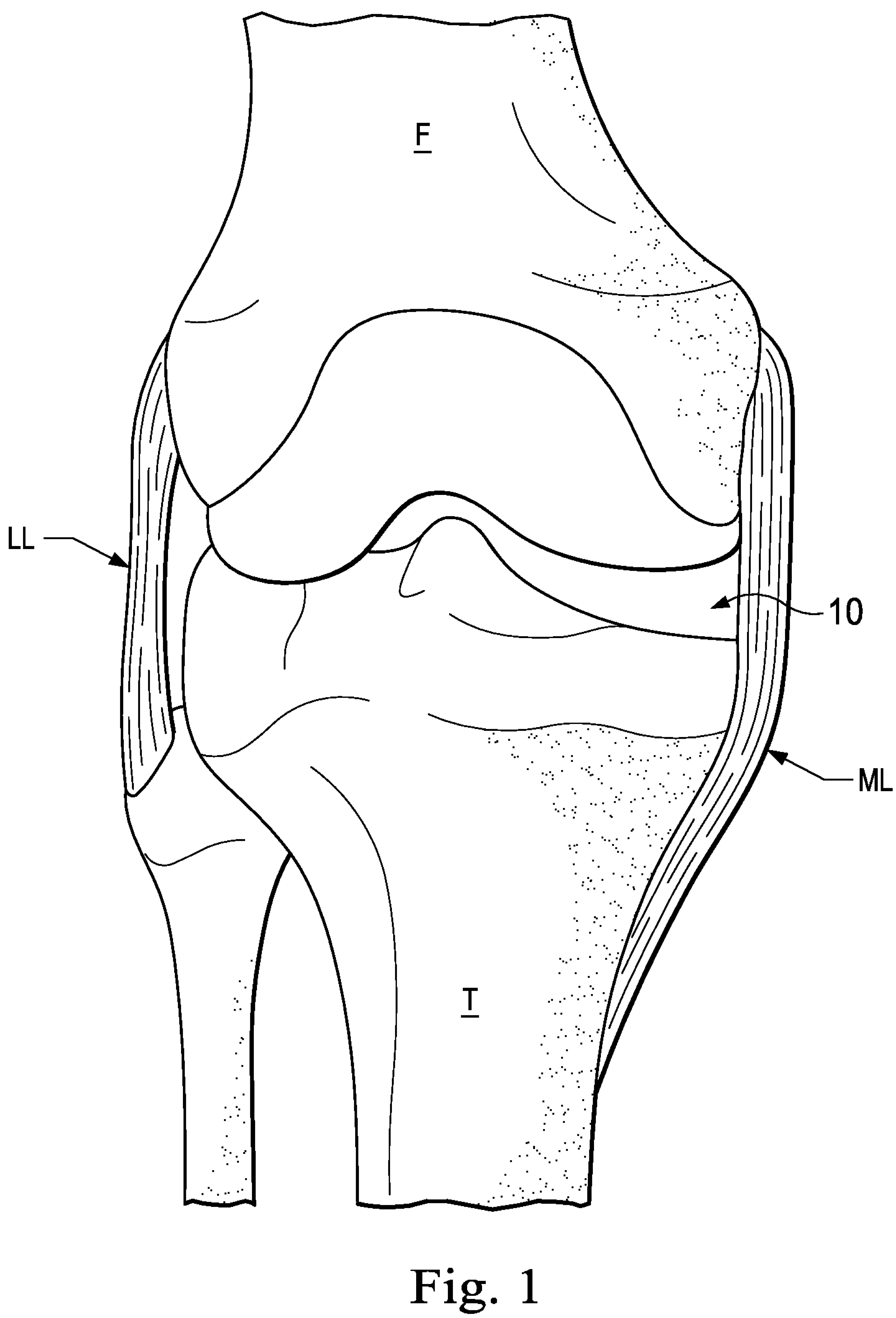


Fig. 1

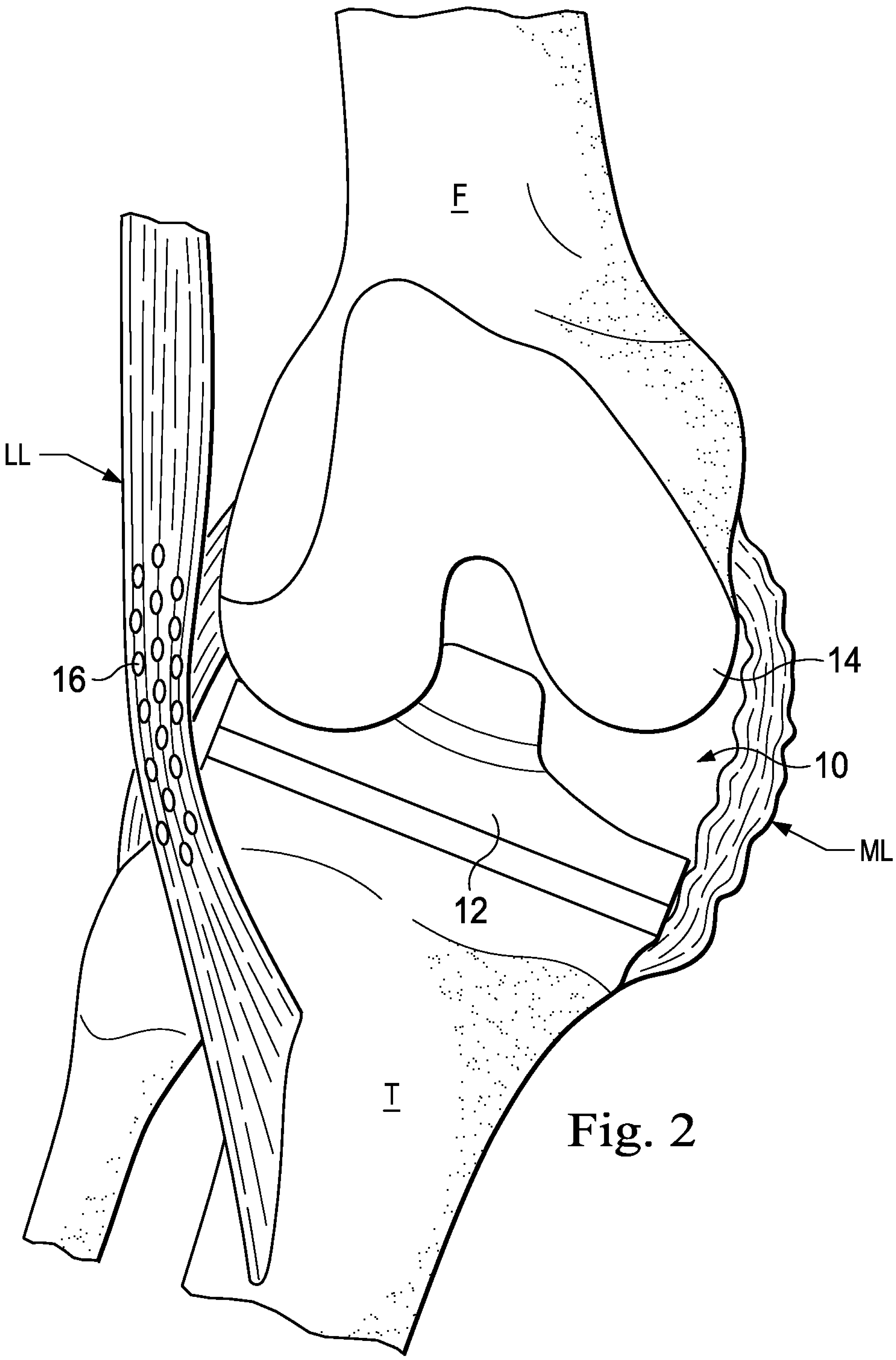


Fig. 2

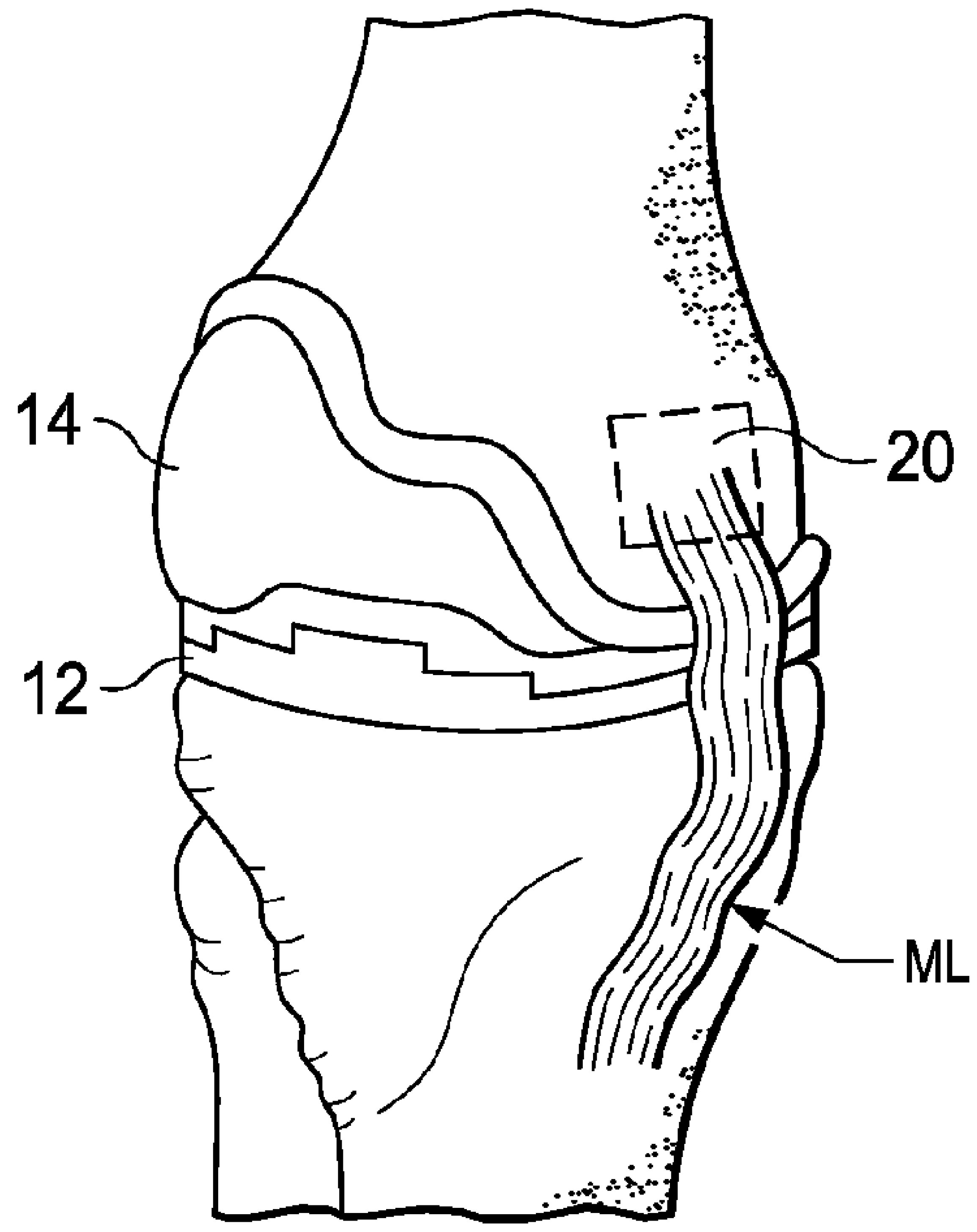


Fig. 3A

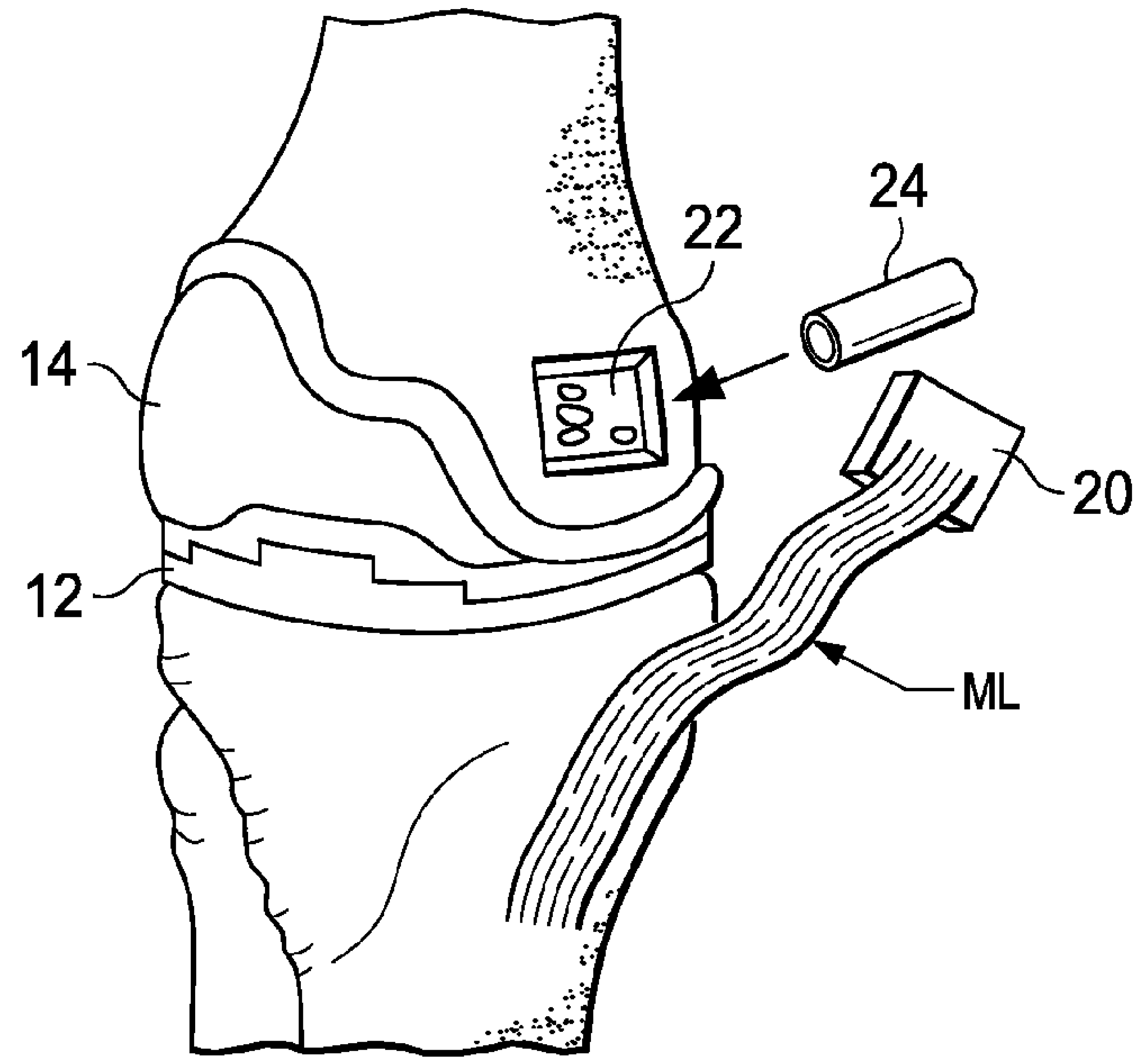


Fig. 3B

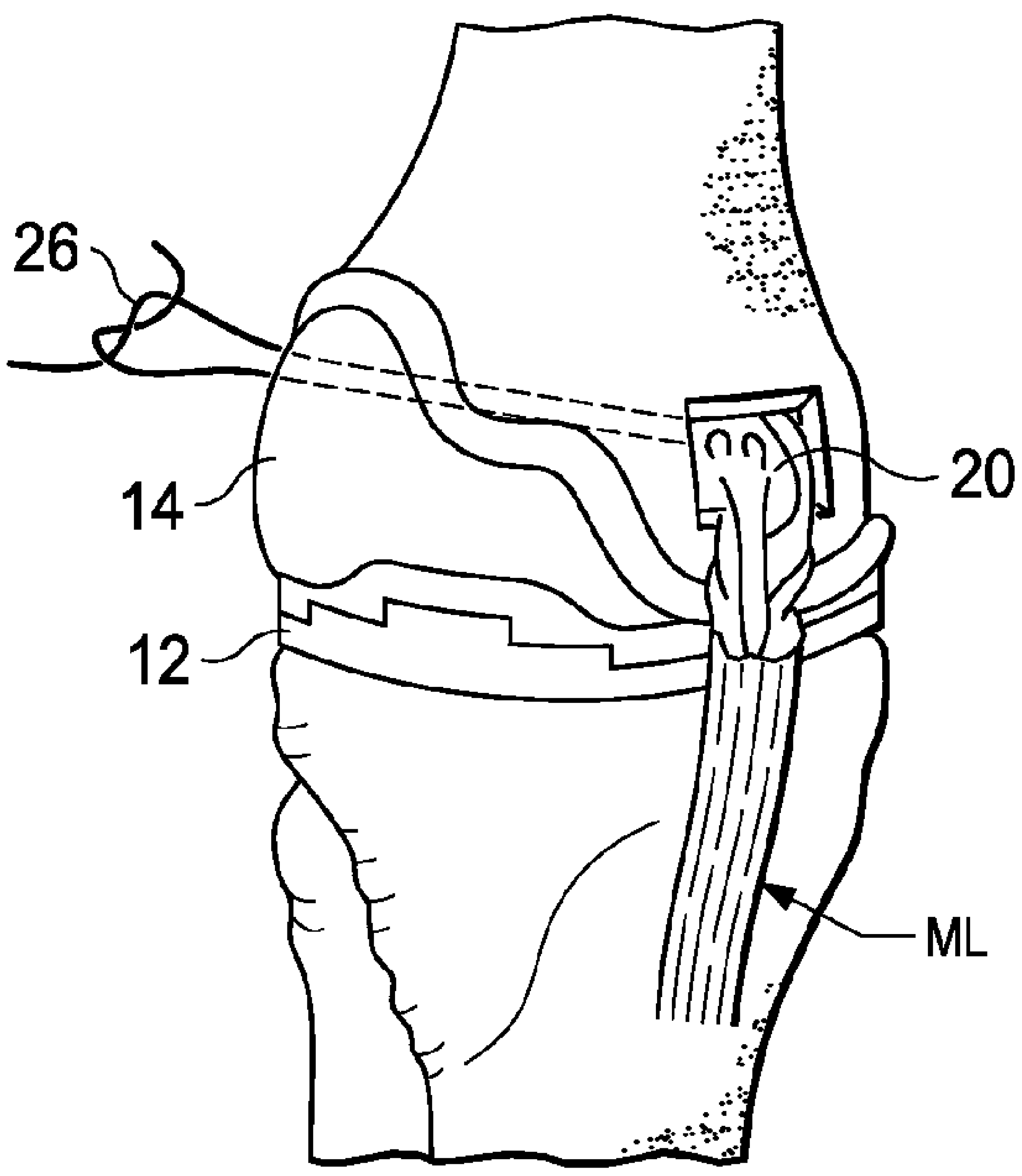


Fig. 3C

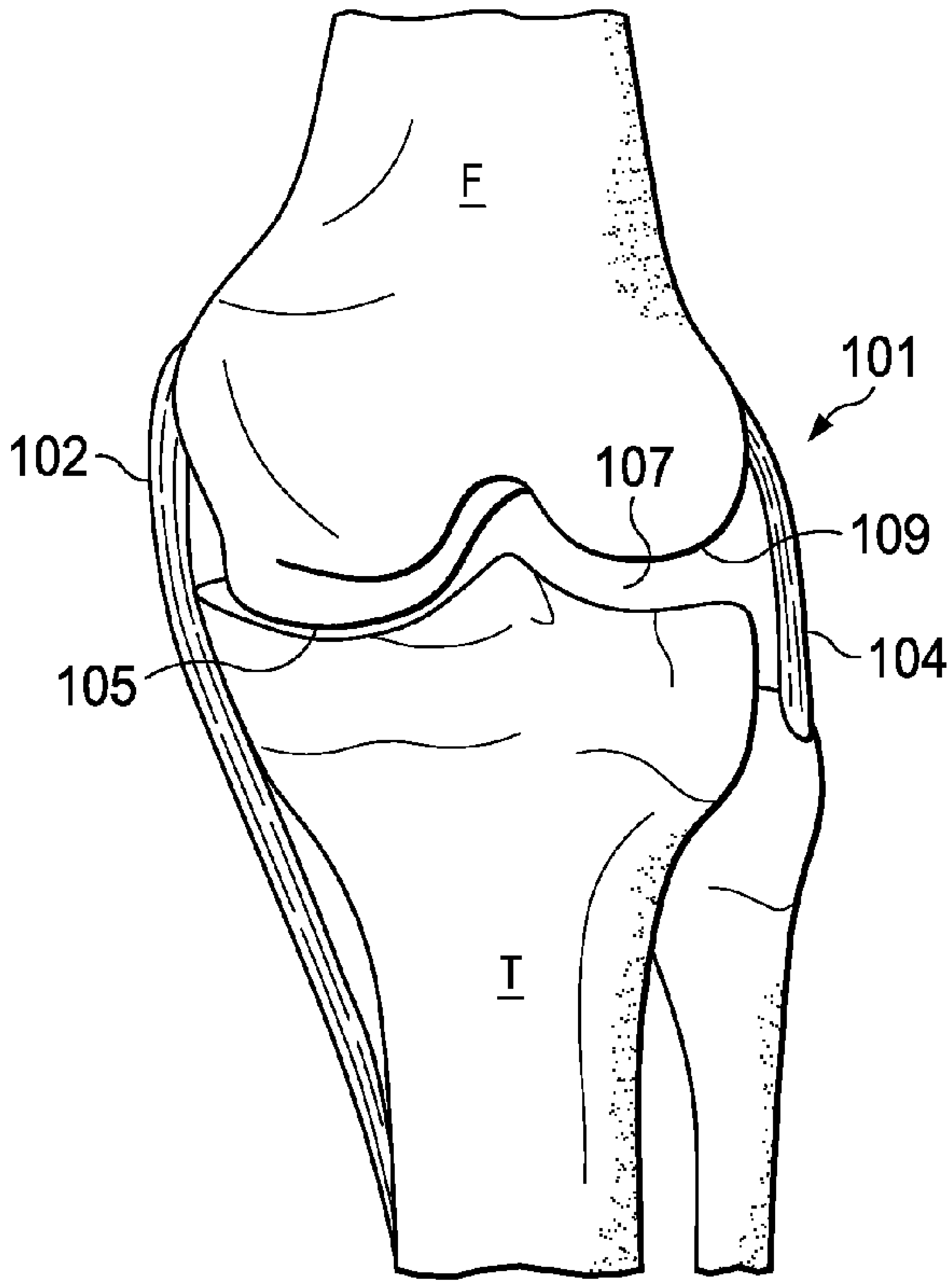


Fig. 4A

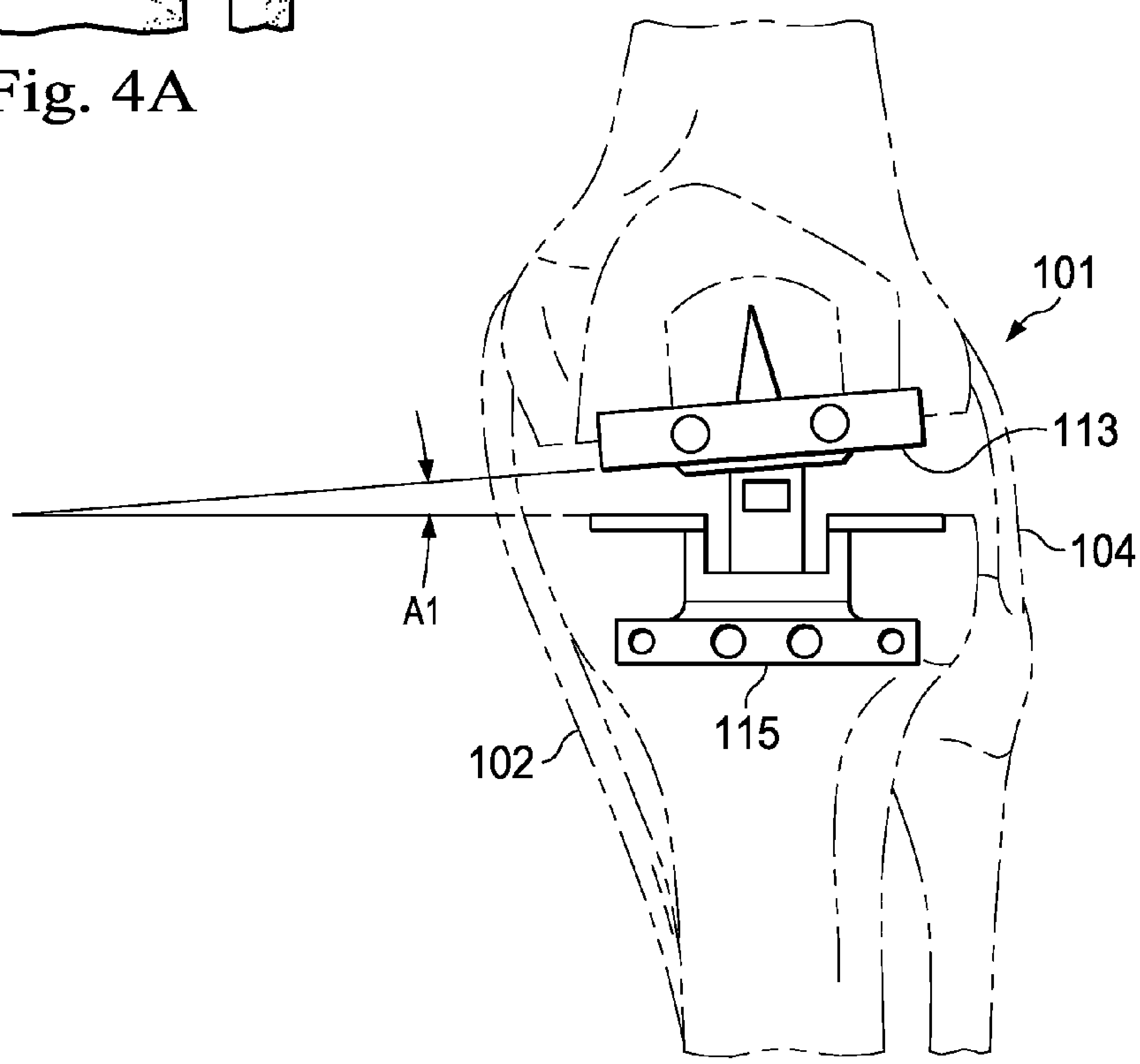


Fig. 4B

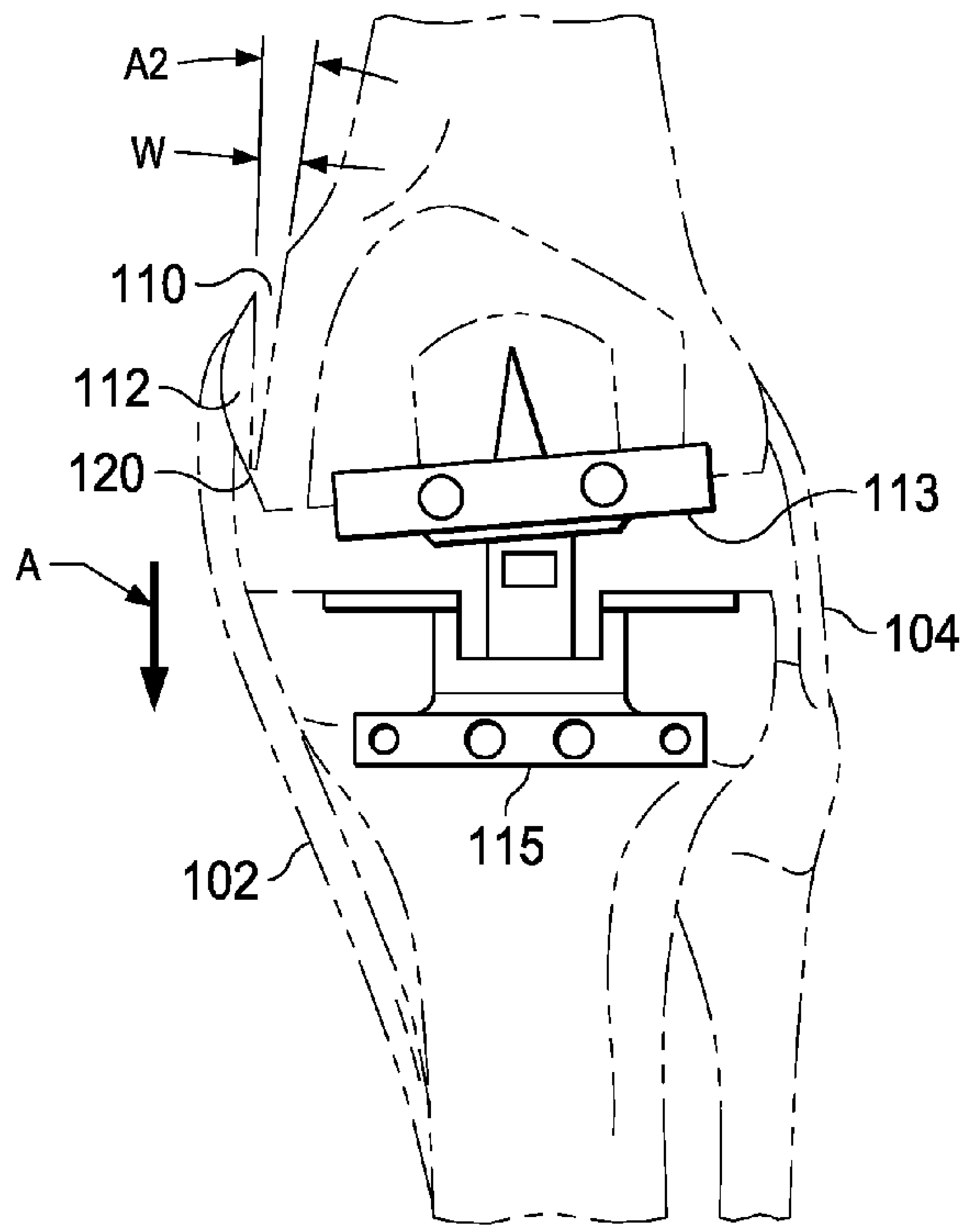


Fig. 4C

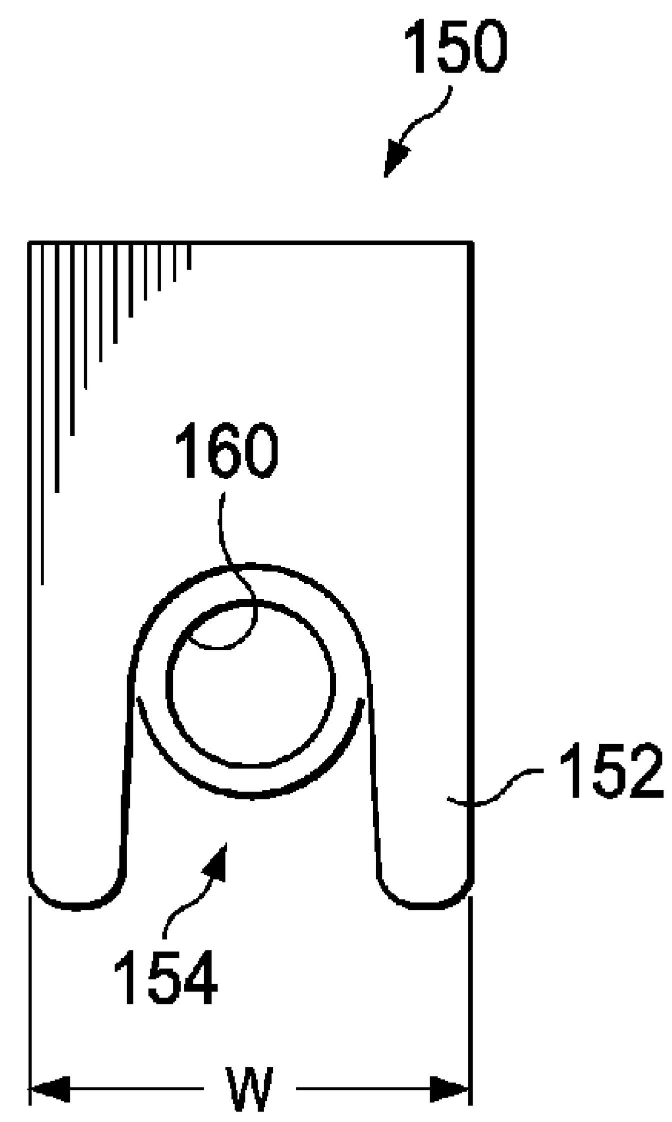


Fig. 5A

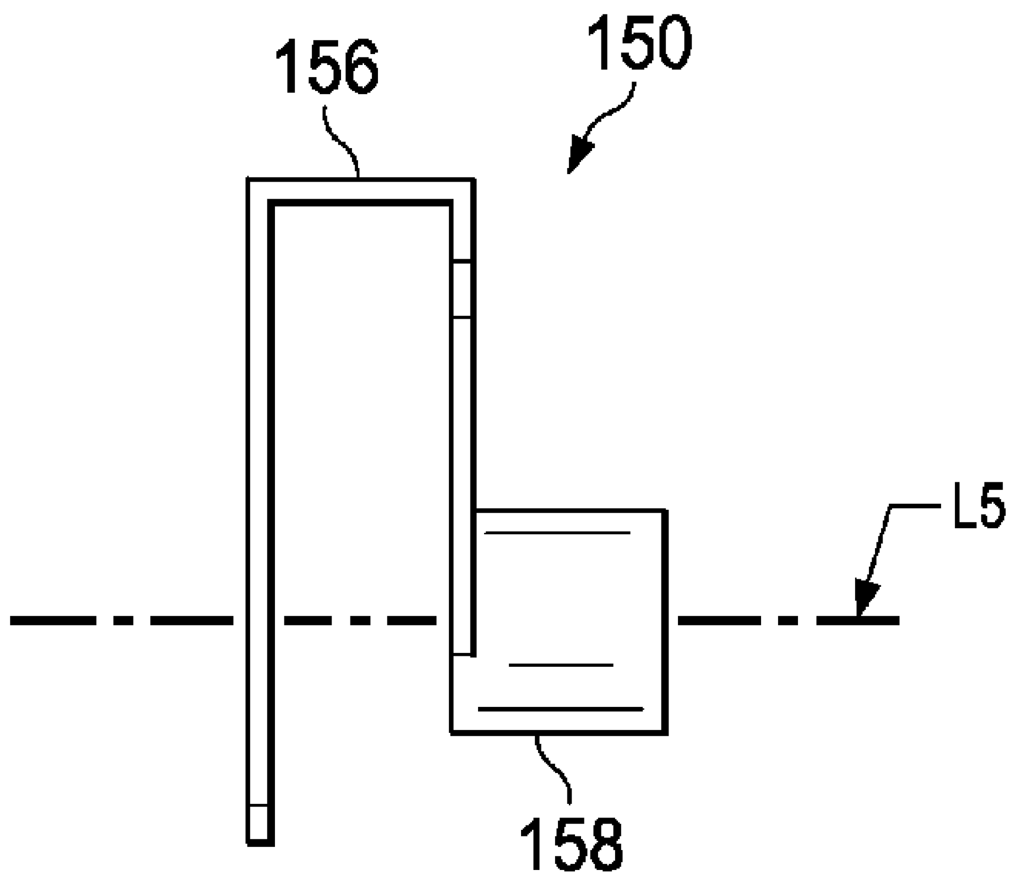


Fig. 5B

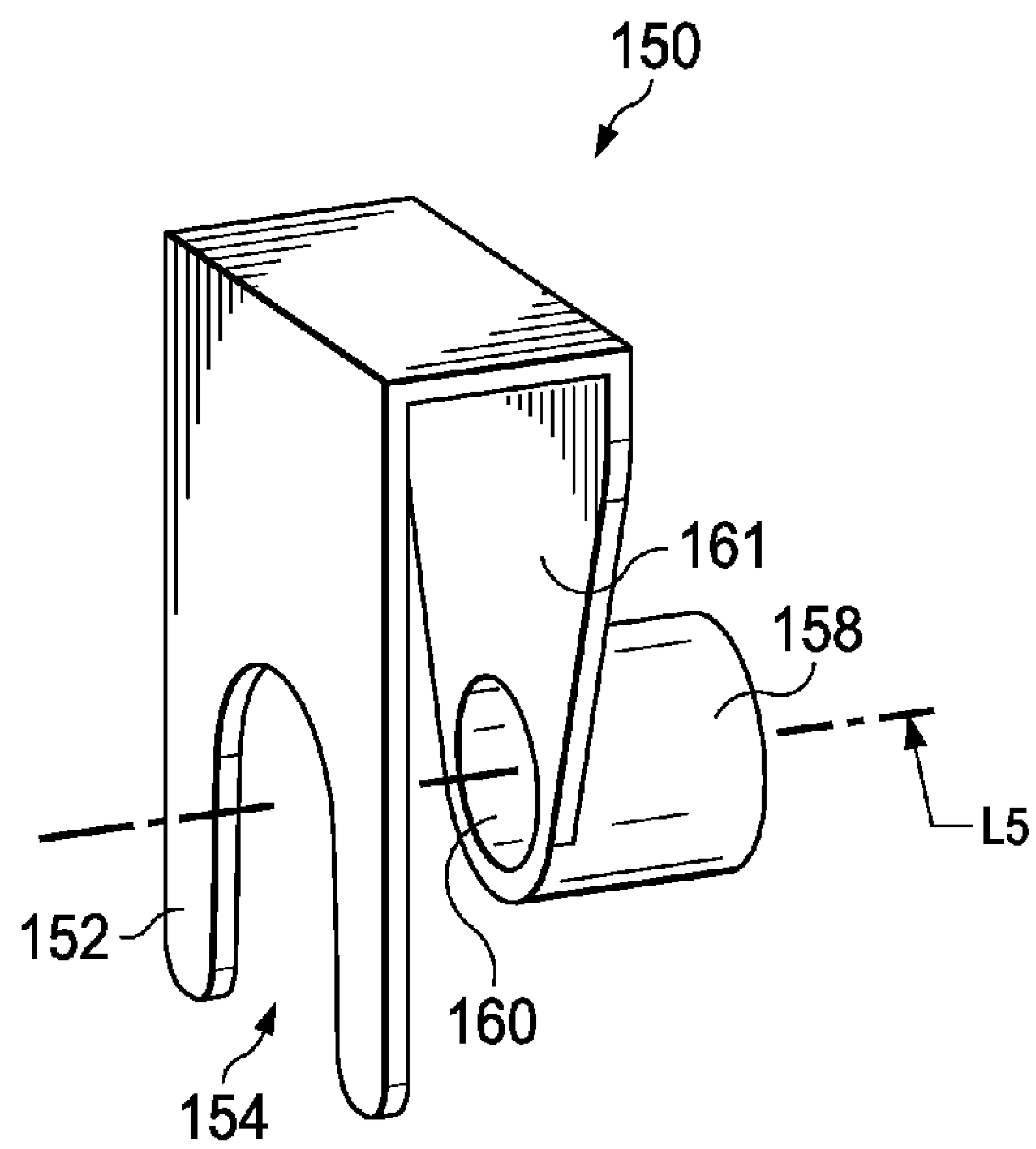


Fig. 5C

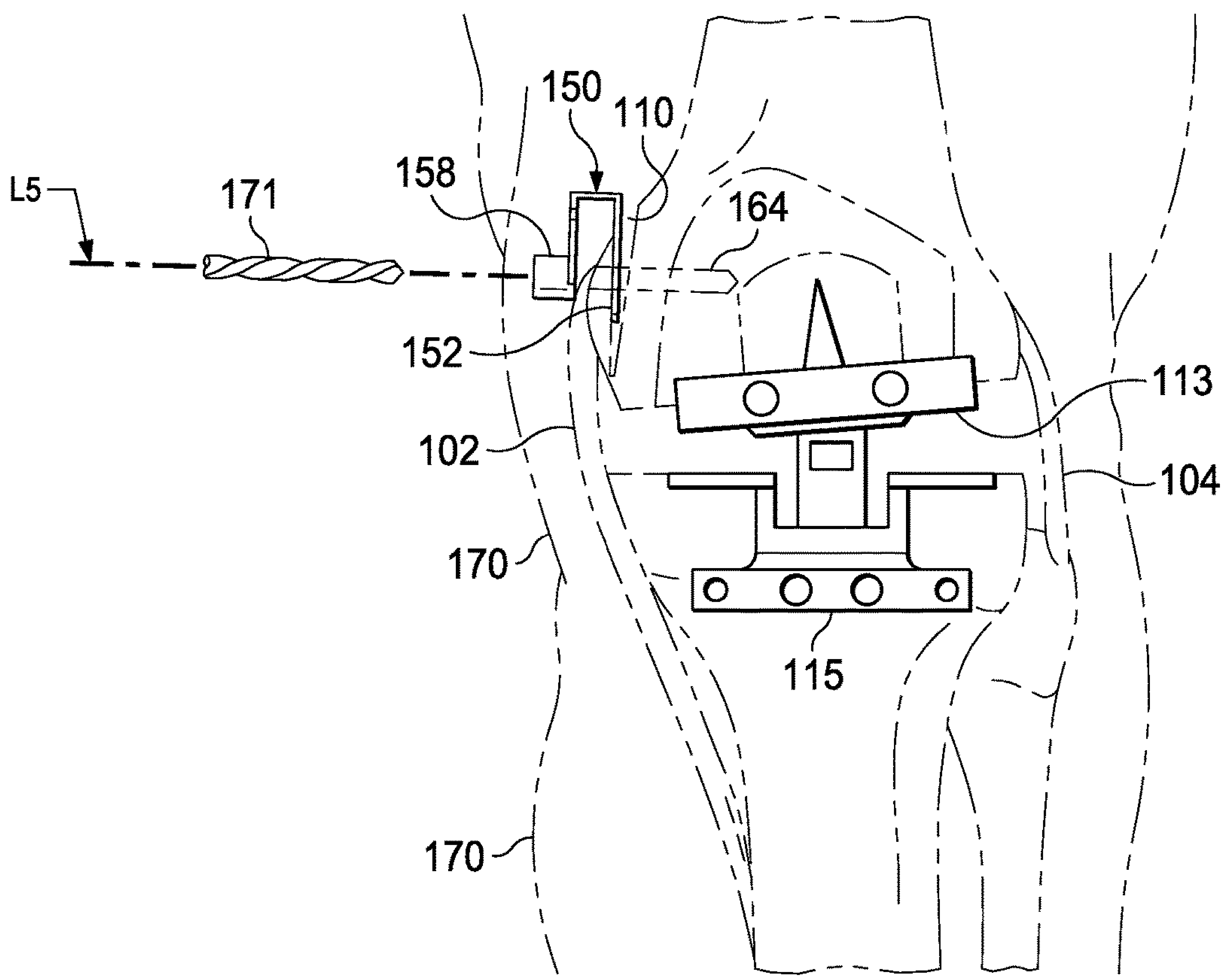


Fig. 6

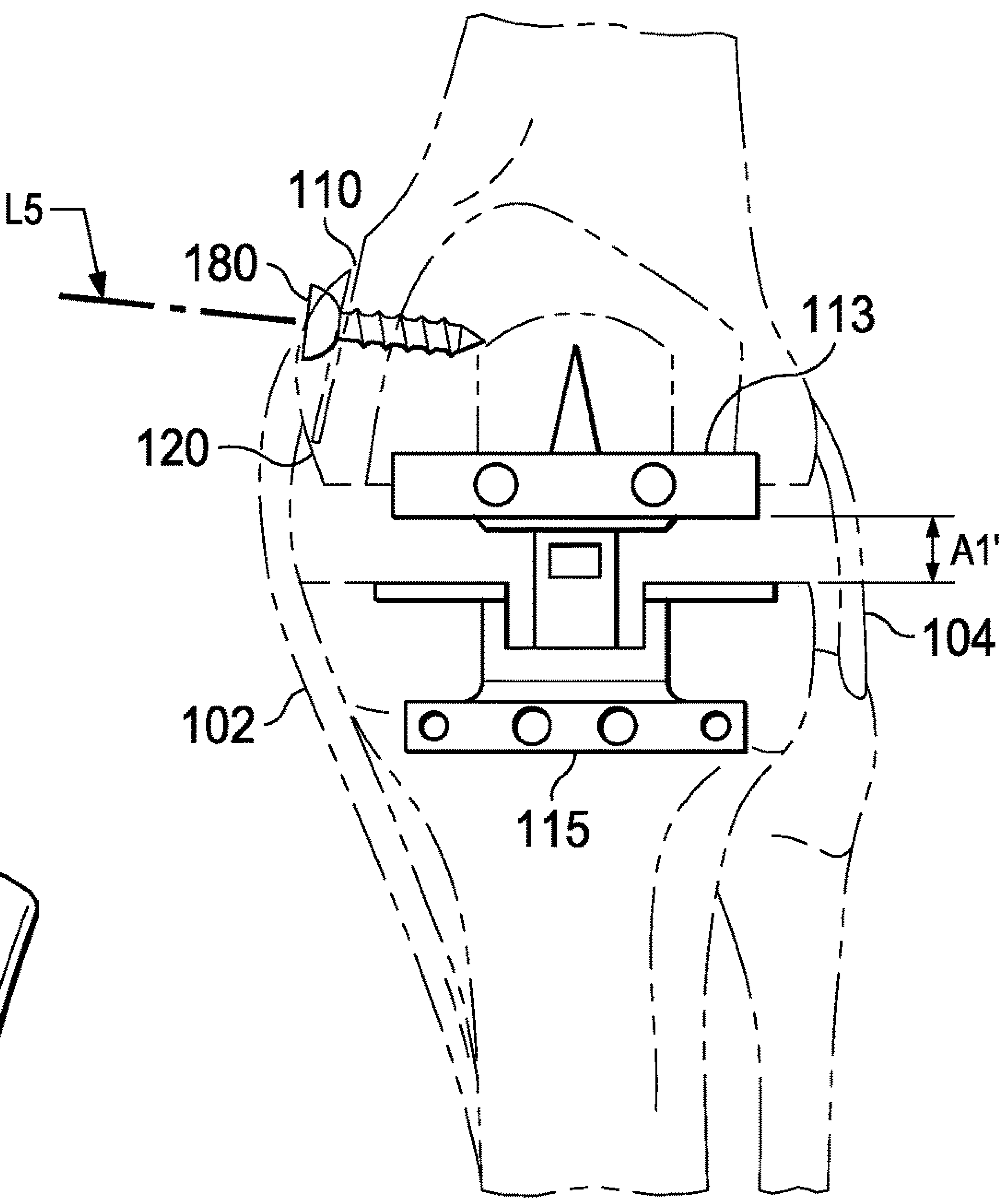


Fig. 7

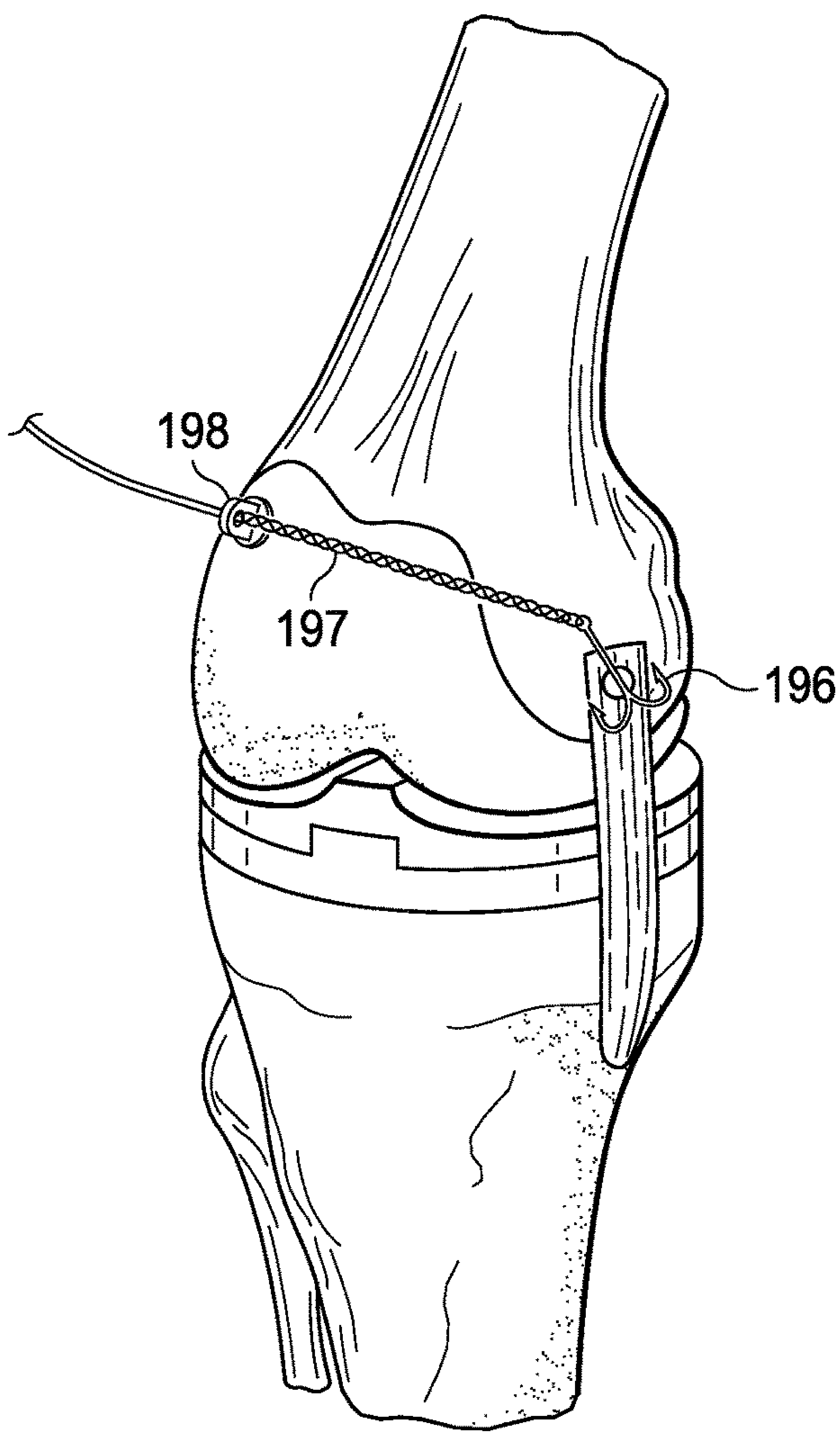


Fig. 8

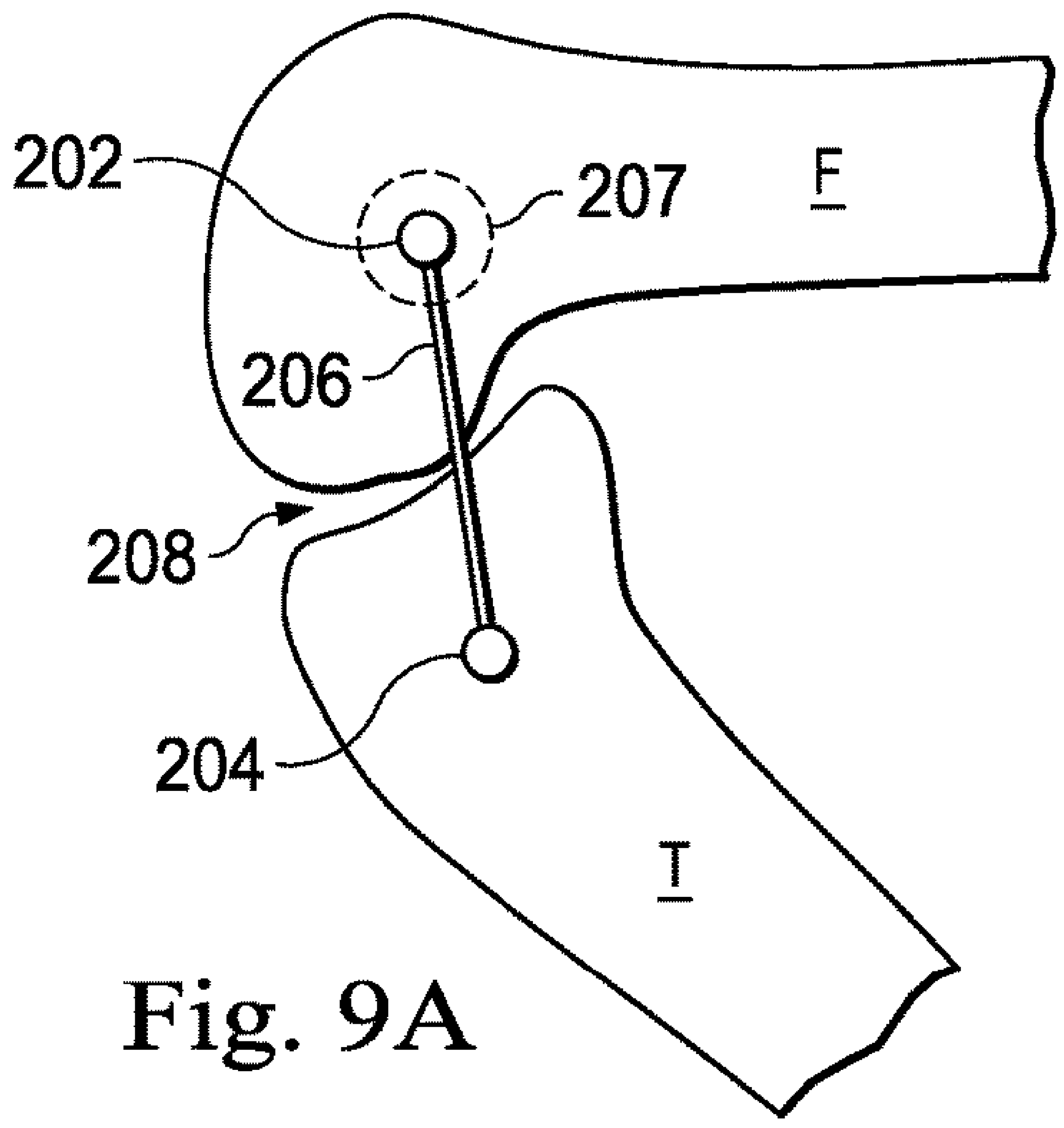


Fig. 9A

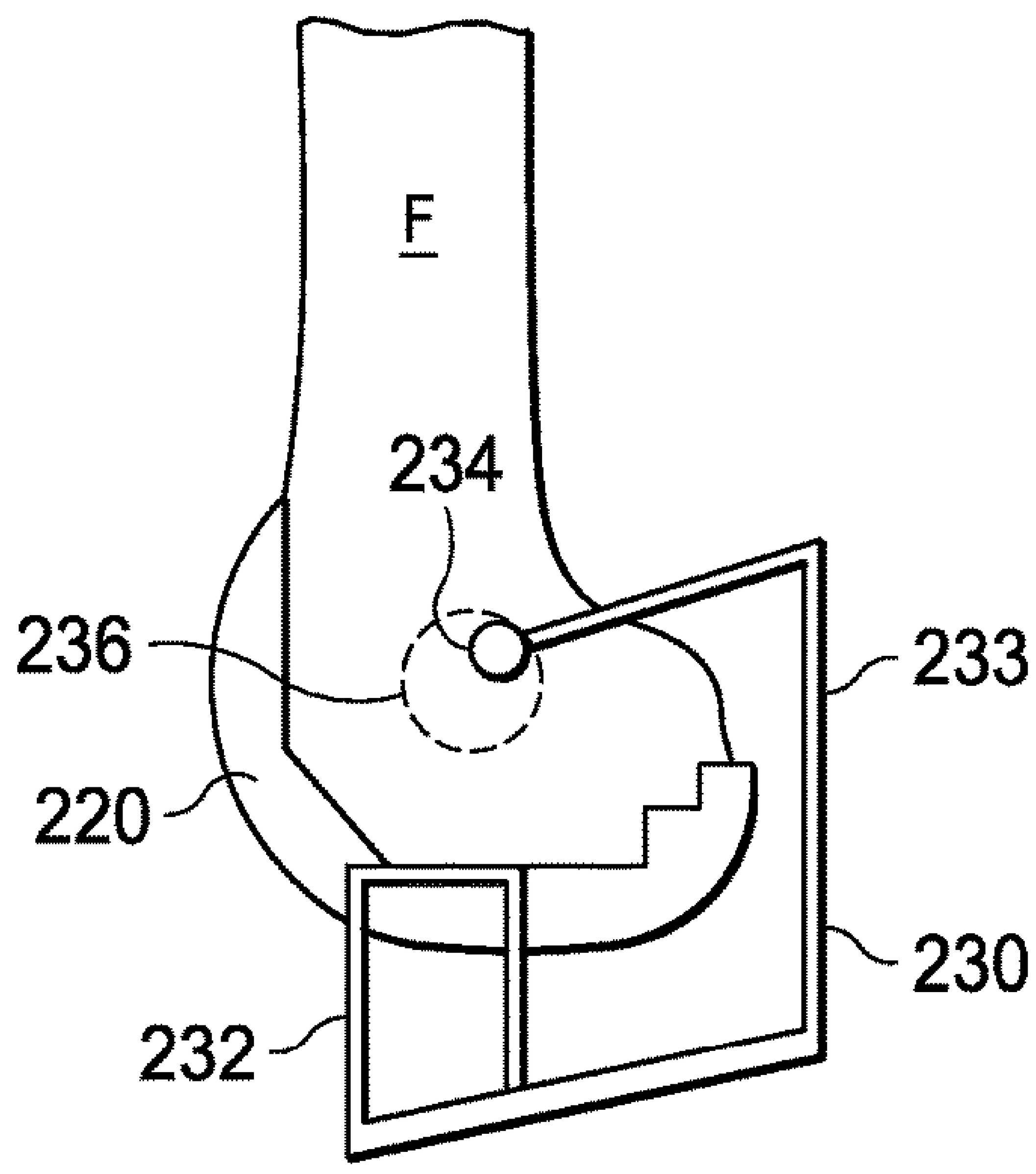


Fig. 10

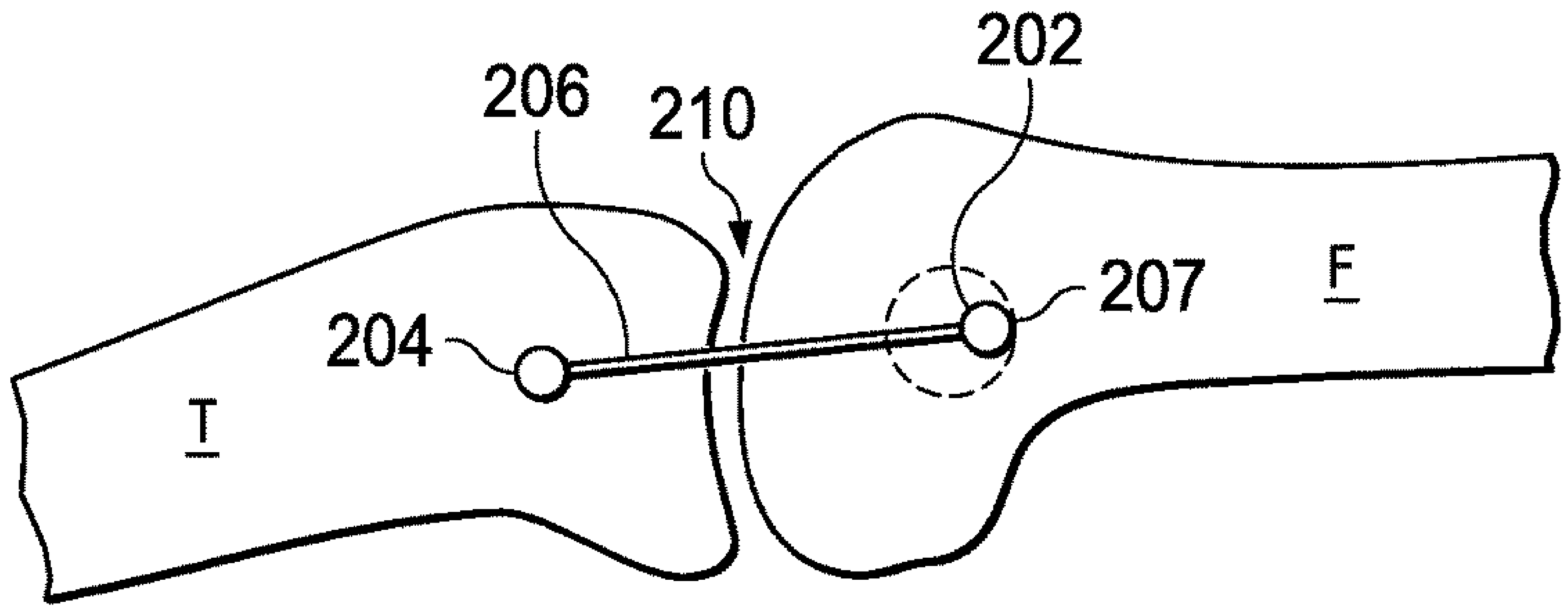


Fig. 9B

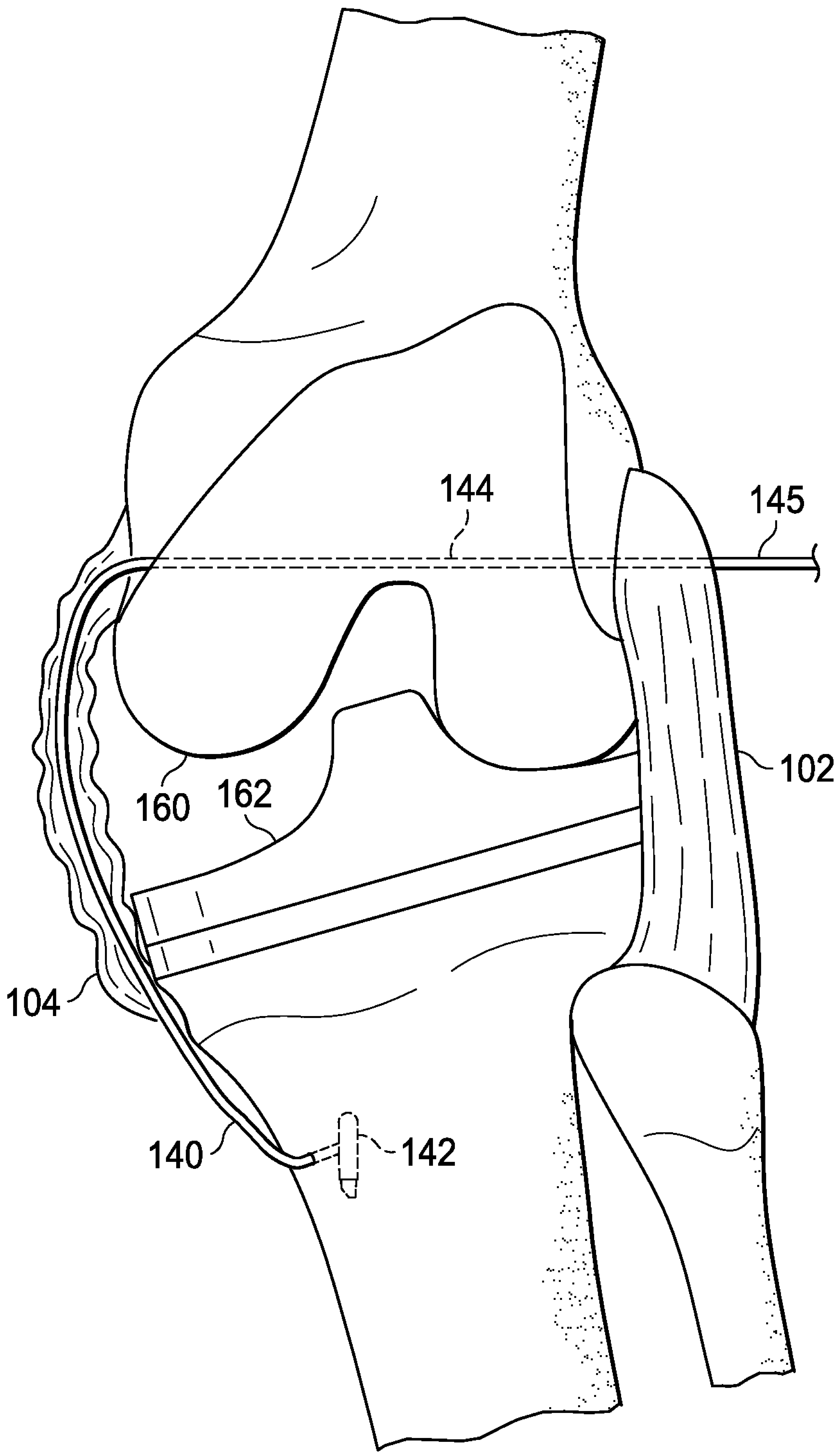


Fig. 11

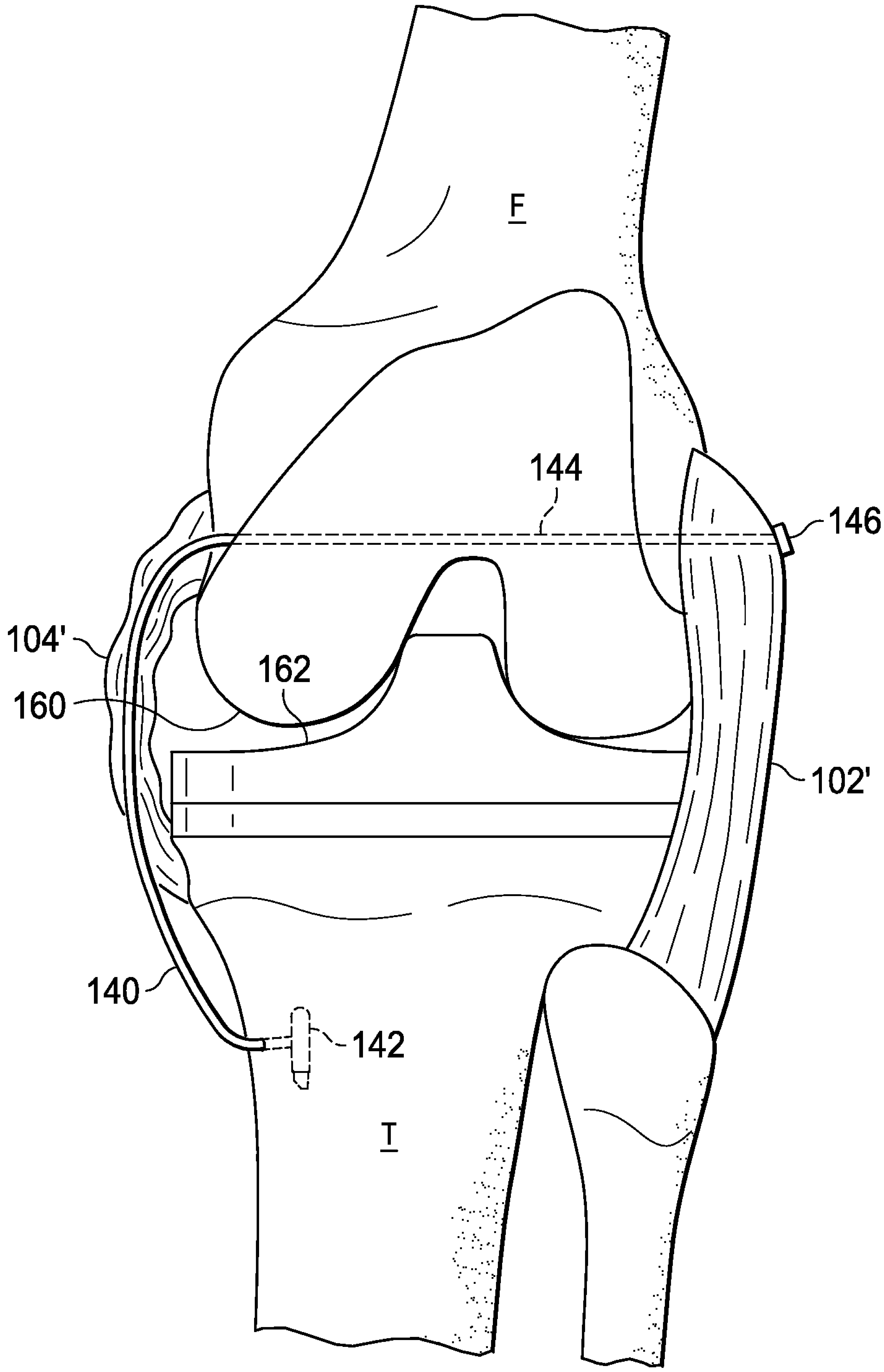


Fig. 12

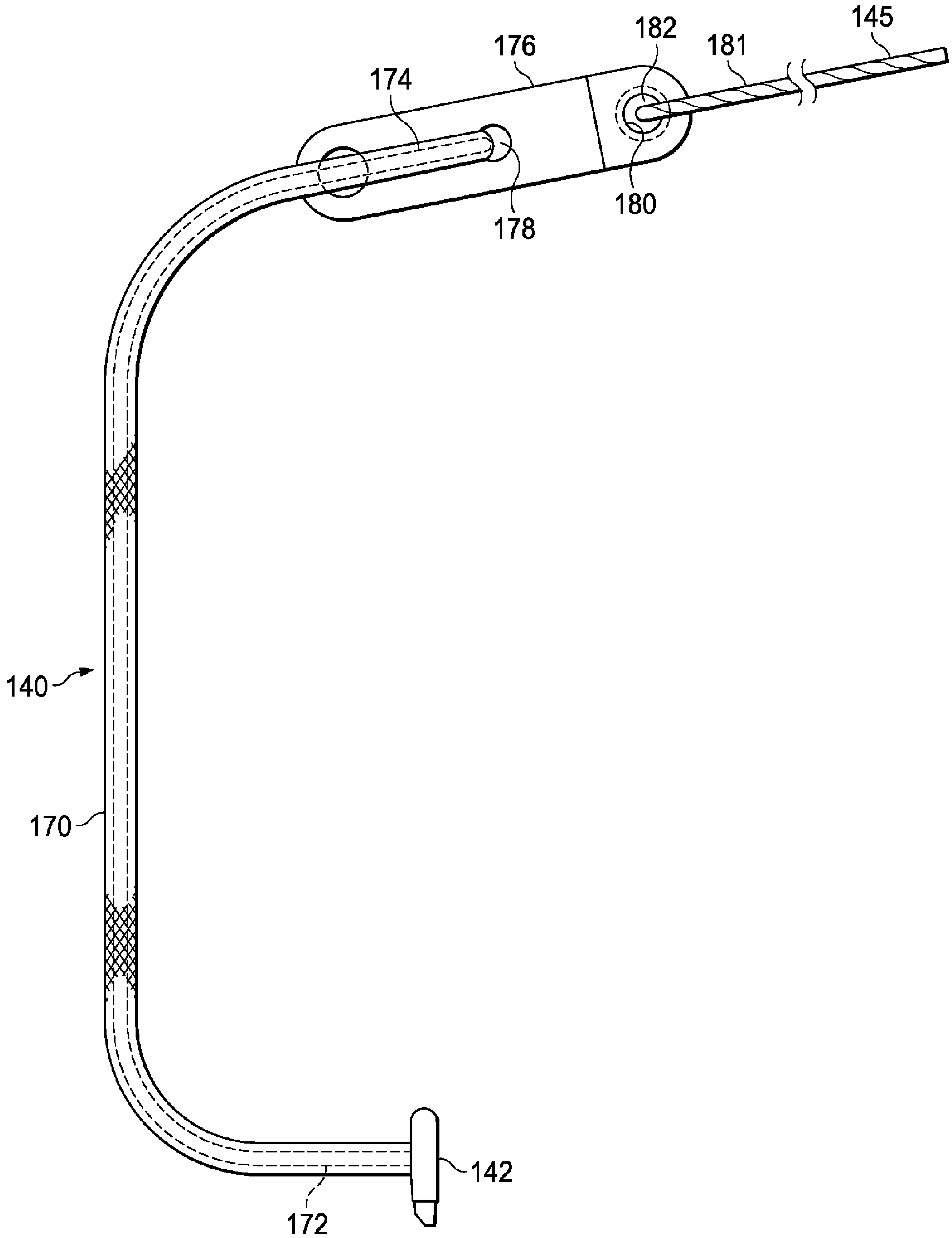


Fig. 13

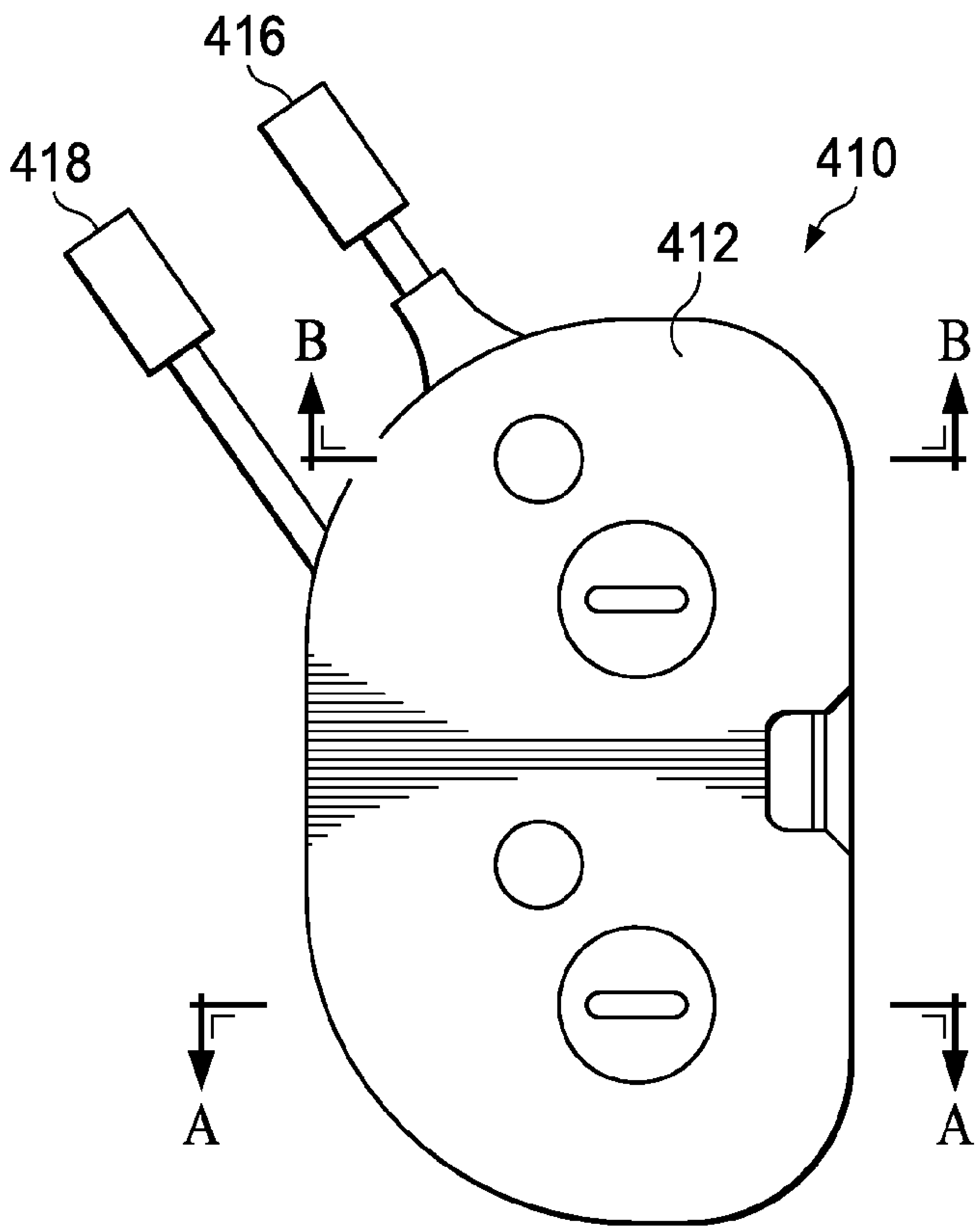


Fig. 14A

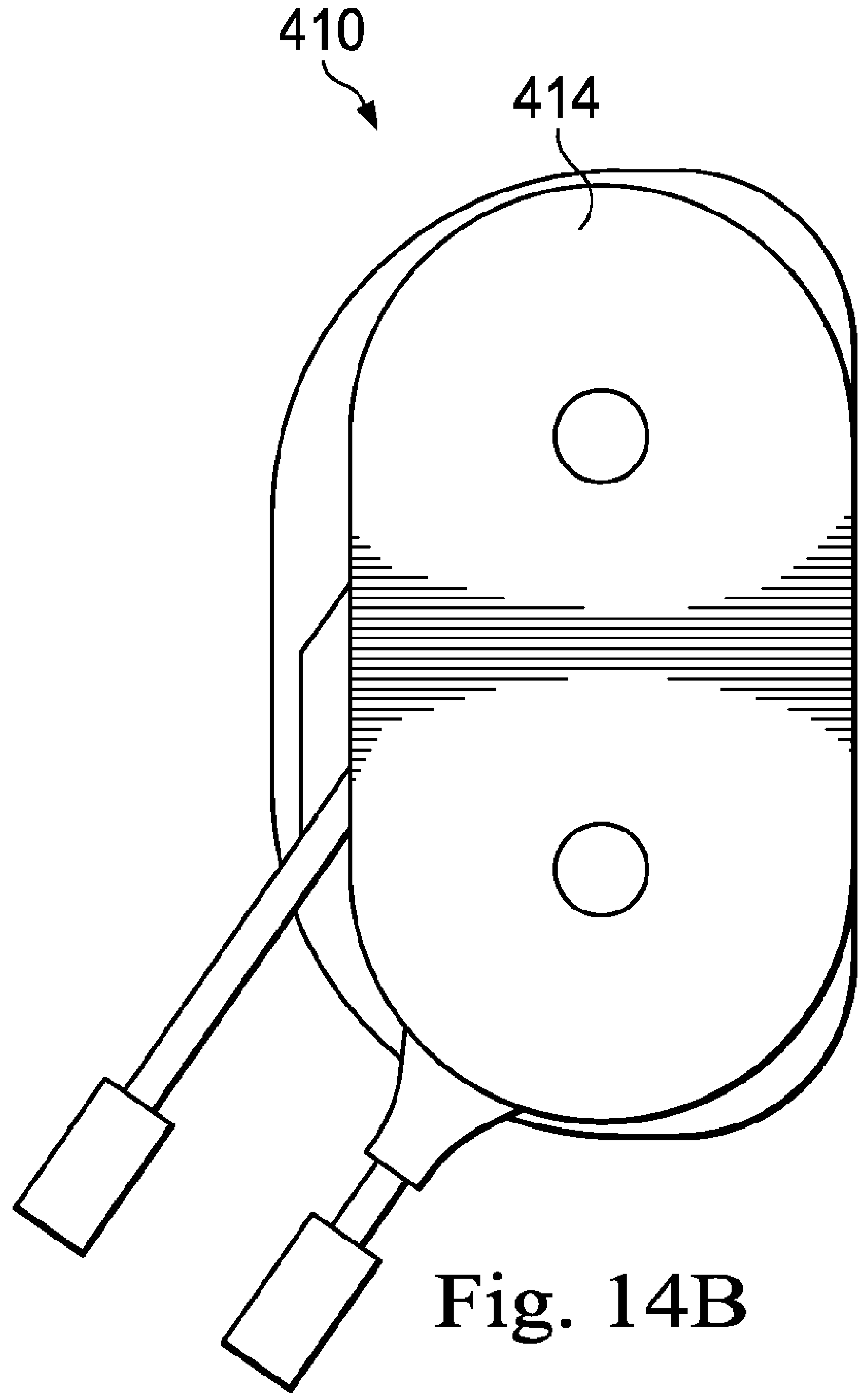


Fig. 14B

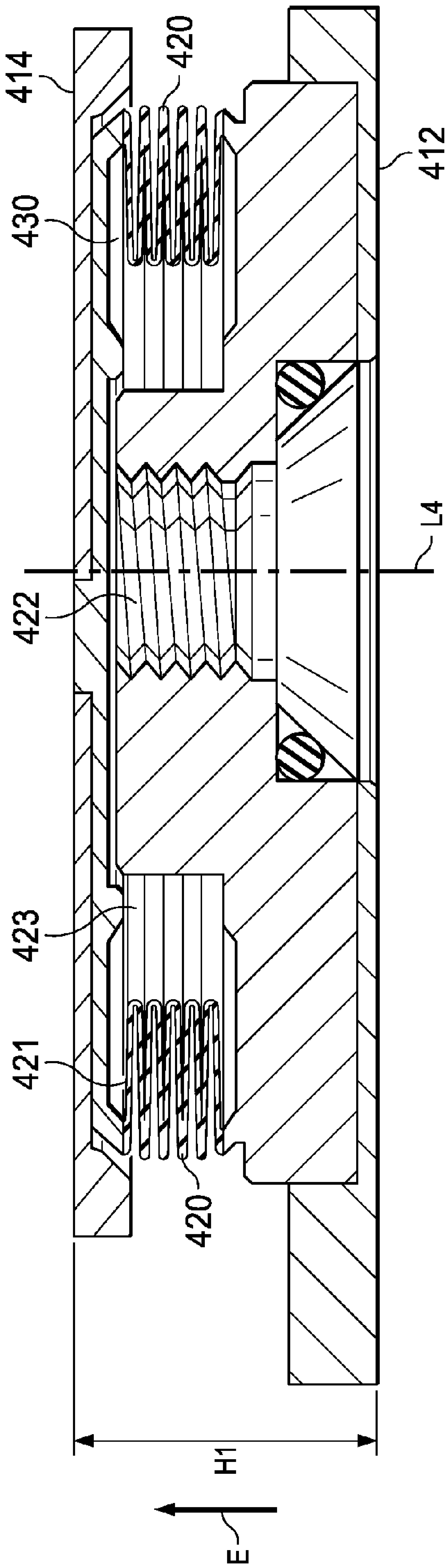


Fig. 15A

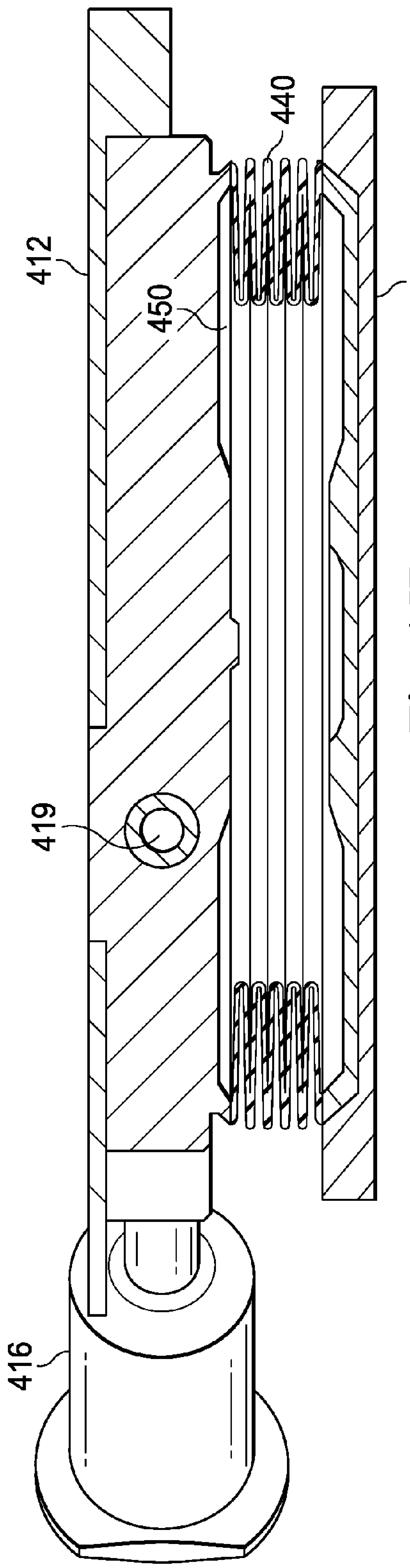


Fig. 15B

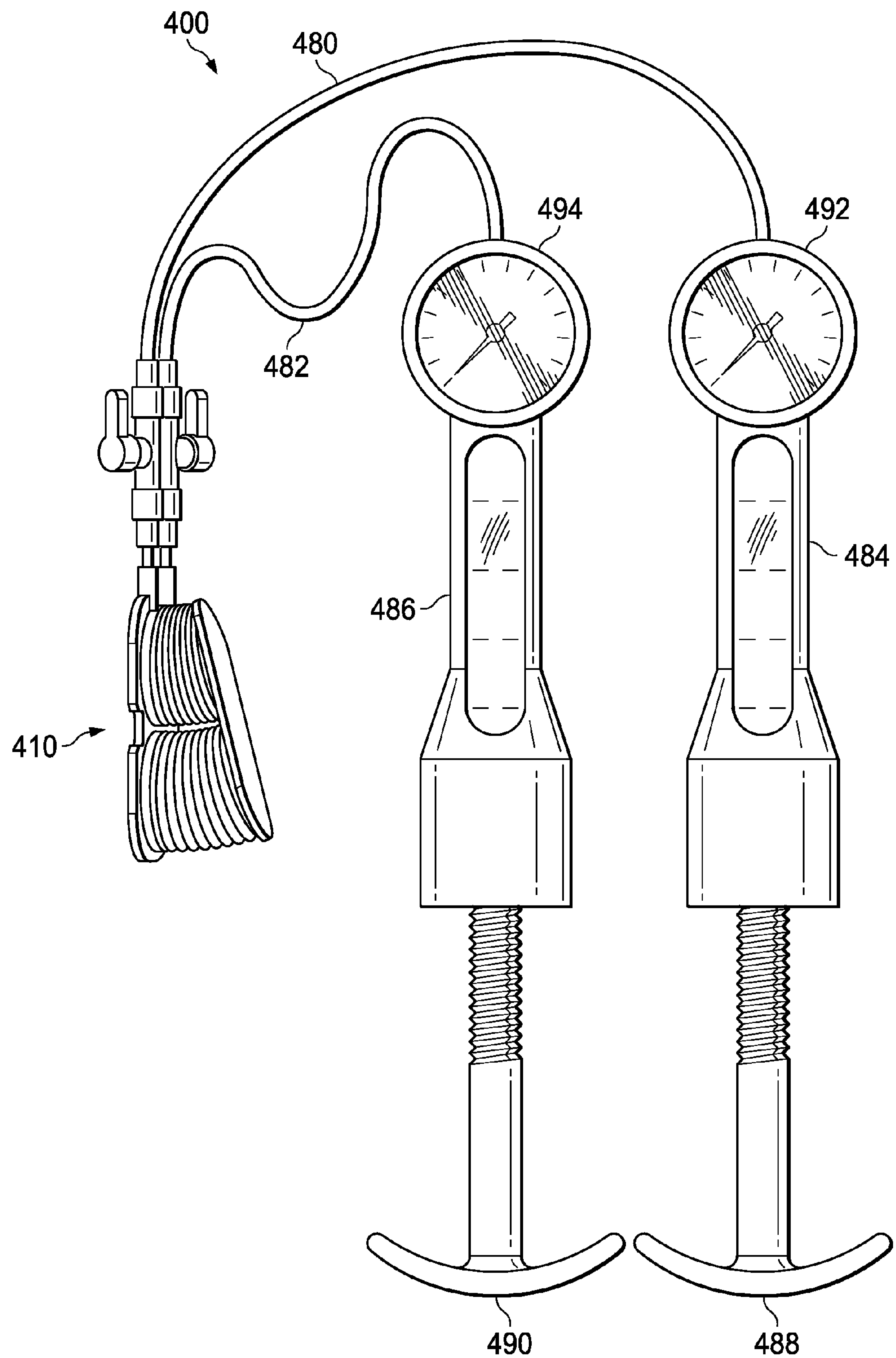


Fig. 16

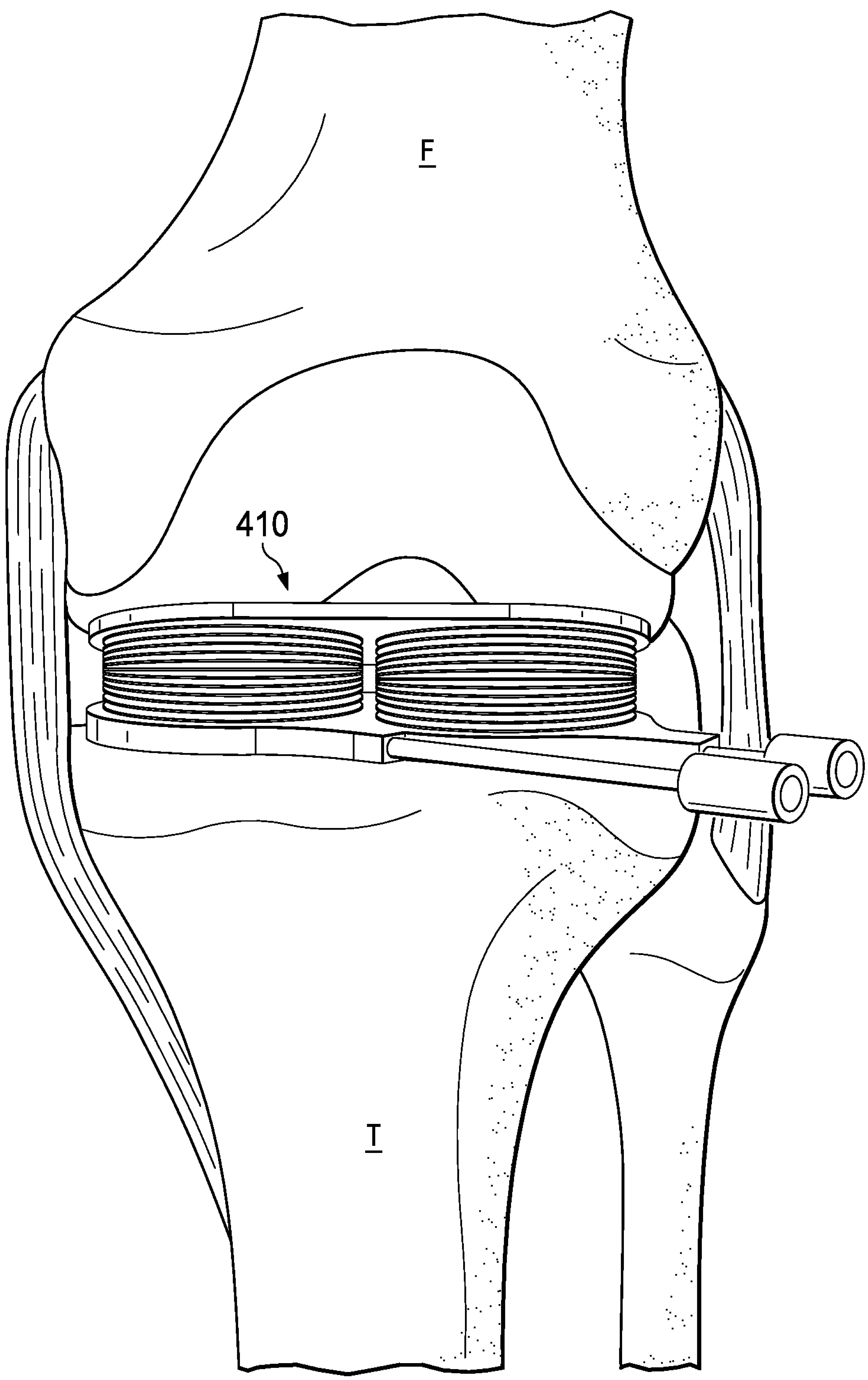


Fig. 17

SYSTEM AND METHOD FOR LOAD BALANCING IN KNEE REPLACEMENT PROCEDURES

This application claims priority to and the benefit of the filing date of U.S. Patent Application No. 62/032,458 filed Aug. 1, 2014, titled "System and Method for Load Balancing in Knee Replacement Procedures" which is incorporated herein by reference in its entirety.

BACKGROUND

Knee ligament balancing is necessary for long term successful total knee function. Valgus and varus knee arthritis is associated with variable degrees of ligament contracture on the worn side and attenuation or laxity of the ligaments on the opposite compartment. If not addressed either limb mal-alignment or knee instability is expected. Therefore ligament lengthening or release should be performed in most total knee procedures. Problems with ligament imbalance are known to lead to accelerated poly wear, pain instability and stiffness.

Currently no consensus exists regarding the best method to produce a balanced knee. Many differing techniques and sequences for ligament release have been reported over the years. New tools have been introduced to help the surgeon; for example, computer-assisted surgery and tensor balancers. However, randomized control trials comparing different techniques, sequences, and tools are limited. The best method of achieving the balanced knee is yet to be determined

In one example of an arthritic knee, the worn lateral side has a tight collateral ligament while the superficial medial collateral ligament on the less worn side is too loose. With reference to FIG. **1**, in addition to any cartilage damage on the condyles, the knee is misaligned such that the lateral ligament LL is too short or tight, while medial ligament ML is too long or lax to properly maintain the alignment of the knee. As shown, the joint **10** between the femur F and the tibia T is misaligned.

Referring to FIG. **2**, the knee joint of FIG. **1** is illustrated with prosthetic knee components **12** and **14** positioned in the joint. Utilizing a prior art technique, pie cuts **16** are made in the lateral ligament LL to lengthen the ligament to attempt to achieve re-alignment of the knee joint. However, as shown this technique does not address the laxity of medial ligament ML. Moreover, the cuts in the LL ligament tend to weaken the ligament which may lead to rupture.

Referring to FIGS. **3A-3C**, a technique is illustrated for shortening the medial ligament ML by cutting out a bone block **20** with attached ligament, removing cancellous bone with instrument **24**, and recessing the medial collateral ligament origin into the metaphyseal bone opening **22** of the femur. The bone block **20** may be held in place by suture **26** extending through the femur.

Methods of knee ligament balancing are still controversial and there remains a need for improvement devices and methods for obtaining a balanced knee.

SUMMARY

In one aspect, the present disclosure provides a system for load balancing in knee replacement procedures. The system comprises a ligament release portion including an epicondylar osteotomy fixation guide and an epicondylar osteotomy fixation member, along with a ligament tension portion including an elongated ligament tension element having a first anchoring element disposed near an inferior end and configured for anchoring below the knee joint, and a femoral anchoring portion for movably anchoring the elongated ligament tension element to the femur.

In another aspect, the present disclosure provides a method for load balancing in knee replacement procedures. The method comprises evaluating ligament balance in a knee and loosening a first over tight ligament on a first side of the knee by performing a partial epicondylar osteotomy adjacent a bone/ligament attachment point of the first ligament by severing a superior portion of the bone adjacent the bone/ligament attachment point while leaving an inferior portion of the bone adjacent the bone/ligament attachment point connected to the native epicondylar bone to thereby form a bone flap positioned over a bone defect. The method includes adjusting the tension on the first ligament by effectively lengthening the first ligament by moving the bone/ligament attachment point on the bone flap inferiorly toward the foot; and fixing the bone flap with interconnected bone/ligament attachment point to the epicondyle to maintain the position of the bone flap relative to the epicondyle to thereby fix the new effective length of the first ligament.

In yet a further aspect, the present disclosure provides a method for load balancing in knee replacement procedures. The method comprises evaluating ligament balance in a knee and identifying a loose ligament that is too lax to properly function to support the knee after insertion of a knee replacement device. The method further includes anchoring an inferior end portion of an elongate ligament support member below the knee, extending the elongate ligament support member along the loose ligament, evaluating tension of the elongate ligament support member in at least one of flexion and extension of the knee to determine the appropriate tension on the elongate ligament support member, and fixing a superior portion of the elongate ligament support member to the femur to maintain the appropriate tension.

In yet a further aspect, the present disclosure provides a knee load balancing instrument. The balancing instrument comprises a first bellows having a first upper bone engaging end plate and a first lower bone engaging endplate and a first movable sidewall joining the first upper and lower bone engaging plates along a longitudinal axis, the first movable sidewall formed of corrugated material inhibiting outward expansion and permitting longitudinal expansion, the first upper and lower bone engaging plates along with the first movable sidewall joined to form a fluid tight first fluid chamber. The instrument preferably also includes a second bellows having a second upper bone engage end plate and a second lower bone engaging endplate and a second movable sidewall joining the second upper and lower bone engaging plates along the longitudinal axis, the second movable sidewall formed of corrugated material inhibiting outward expansion and permitting longitudinal expansion, the second upper and lower bone engaging plates along with the second movable sidewall joined to form a fluid tight second fluid chamber. The instrument includes a first tube joined to the first fluid chamber and configured for connection a first pump; and a second tube joined to the second fluid chamber and configured for connection a second pump, wherein the first fluid chamber and associated first movable sidewall is movable longitudinally independently from the second fluid chamber and second movable sidewall.

These and other aspects of the present disclosure will be apparent from the following disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates a front view of a knee with improper alignment and ligament balance.

FIG. **2** illustrates the knee of FIG. **1** with knee replacement device inserted and a prior art technique utilized to lengthen the shortened ligament on the lateral side.

FIGS. **3**A-**3**C illustrate the knee of FIG. **1** with a knee replacement device inserted and a prior art technique being employed to shorten the lax ligament on the medial side.

FIGS. **4**A-**4**C illustrate a knee being prepared to receive a knee replacement device and a new technique according to the present disclosure for lengthening the ligament on the shortened side.

FIGS. **5**A-**5**C are various views of an epicondylar drill guide.

FIG. **6** illustrates the drill guide of FIGS. **5**A-**5**C positioned in an epicondylar defect of the knee illustrated in FIG. **4**C.

FIG. **7** illustrates the knee of FIG. **4** with a screw inserted to maintain the position of the partial epicondylar osteotomy bone flap.

FIG. **8** illustrates a further fixation device suitable for fixing the partial epicondylar osteotomy bone flap.

FIG. **9**A illustrates an elongate ligament replacement positioned between the femur and tibia in flexion.

FIG. **9**B illustrates an elongate ligament replacement positioned between the femur and tibia in extension.

FIG. **10** illustrates a drill guide associated with a femor component of a knee replacement device positioned in the knee joint.

FIG. **11** illustrates a knee with a knee replacement device positioned in the joint, the knee being misaligned and the medial ligament being lax.

FIG. **12** illustrates the knee of FIG. **11** with the implementation of the ligament tightening system and method to bring the knee into alignment.

FIG. **13** illustrates an elongate ligament replacement for use in one embodiment of the present disclosure.

FIGS. **14**A and **14**B illustrate the top and bottom, respectively, of a knee bellows system.

FIG. **15**A is a cross-section of FIG. **14**A taken along line A-A.

FIG. **15**B is a cross-section of FIG. **14**A taken along line B-B.

FIG. **16** illustrates the bellows attached two a pair of pump assemblies configured to independently inflate each bellows.

FIG. **17** illustrates the knee bellows system inserted into a knee joint.

DETAILED DESCRIPTION

For the purposes of promoting an understanding of the principles of the present disclosure, reference will now be made to the embodiments illustrated in the drawings, and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the disclosure is intended. In the following detailed description of the aspects of the invention, numerous specific details are set forth in order to provide a thorough understanding of the disclosed embodiments. However, it will be obvious to one skilled in the art that the embodiments of this disclosure may be practiced without these specific details. In other instances well known methods, procedures, components, and mechanisms have not been described in detail so as not to unnecessarily obscure aspects of the embodiments of the invention.

Any alterations and further modifications to the described devices, instruments, methods, and any further application of the principles of the present disclosure are fully contem-

plated as would normally occur to one skilled in the art to which the disclosure relates. In particular, it is fully contemplated that the features, components, and/or steps described with respect to one embodiment may be combined with the features, components, and/or steps described with respect to other embodiments of the present disclosure. In addition, dimensions provided herein are for specific examples and it is contemplated that different sizes, dimensions, and/or ratios may be utilized to implement the concepts of the present disclosure. To avoid needless descriptive repetition, one or more components or actions described in accordance with one illustrative embodiment can be used or omitted as applicable from other illustrative embodiments. For the sake of brevity, the numerous iterations of these combinations will not be described separately. For simplicity, in some instances the same reference numbers are used throughout the drawings to refer to the same or like parts.

Referring to FIG. **4**A, a knee is shown with a tight ligament **102** and an opposing loose ligament **104** on opposite sides of the knee joint **101**. Referring to the bone structure of the femur F and the tibia T, the medial condyle **105** is in contact with the tibial plateau while the lateral condyle **109** is spaced from the tibial plateau creating a void **107**. As shown in FIG. **4**B, bone has been resected from both the femur F and the tibia T and a trial implant guide has been positioned in the knee joint **101**. As a result of the shortening of ligament **102** and resulting tension, in combination with the lengthening of ligament **104** and resulting laxity, the femoral component **113** of the trial is angled at an initial angle A**1** with respect to the tibial component **115**.

Referring now to FIG. **4**C, in accordance with the present disclosure, a partial epicondylar osteotomy is performed just superior of the attachment of the ligament **102** to the femur F. The osteotomy forms a gap **110** having an initial width W. In one preferred form of the method, the inferior portion **120** the bone block **112** remains attached to the femur such that the gap **110** defines a starting angle A**2** with respect to the remainder of the femur. Force applied on the ligament **102** in the direction of arrow A widens the gap **110** to form a second larger width W effectively lengthening the ligament **102**. As will be appreciated, force in the direction of arrow A will also result in the bone block **112** moving from a first angle Al to a second position with an angle larger than A**1**. The process of lengthening and checking for the proper length can continue until the desired "effective" length of ligament **102** is reached. Often the length is increased until the knee joint is in a balanced position as shown in FIG. **7**. It will be appreciated that the length of ligament **102** does not actually increase, rather it is the movement of the underlying bone attachment **112** that results in an "effective" increase in the length of the ligament. Once the desired width is achieved, a fixation member **130** may be positioned into the femur through the bone fragment **112** attached to ligament **102** to maintain the position of the fragment relative to the femur. As discussed further below, the fragment may be fixed by a screw, nail, cable or suture.

Referring to FIGS. **5**A-**5**C, there is shown an epicondylar osteotomy fixation guide **150**. The guide includes a blade **152** having a width W. In one aspect, the width W is substantially the same as the width of an osteotome saw blade utilized to form the defect in the bone described above, while the thickness of the guide blade is substantially the same as thickness of the saw blade. The guide blade **152** includes a passage **154**. Although shown as an oblong passage, it is contemplated that the blade may include openings through the blade or an indent in the blade edge, provided a drill member can pass through at least a portion of the blade to form an opening in the bone. The guide includes a support arm **156** which extends from the blade **152** and supports a tubular drill guide **158** having an internal passage **160**. The internal passage **160** has a longitudinal axis L**5** that is aligned with the opening **154** in the blade. Drill guide **150** has inner face **161** that is configured for placement facing the exterior of the femoral bone while the blade is configured for placement within a bone opening.

As shown in FIG. **6**, the blade **152** of the drill guide **150** is positioned in the bone defect **110** such that the support arm holds the drill guide **158** outside the femoral bone but under the skin **170** (shown in dash lines). In a preferred aspect, the drill guide has a relatively low profile so the skin and associated soft tissue can slide over the drill guide as the knee is moved through a range of motions. In one aspect, it will be appreciated that a drill bit **171** may pass along the tubular drill guide **158** and be guided into and through opening **154** along longitudinal axis L**5**.

In use, a saw or other instrument is used to create the bone defect or gap **110** while the knee is at approximately a 90 degree flexion position. The osteotomy starting point is at the junction of the distal articular surface and the cortex directed superior. The inferior portion of the bone with the ligament attachment continues to be attached to the femur. Gradual distraction of the knee results in movement of the bone flap **112** inferiorly toward the foot which acts to effectively lengthen the ligament **102**. A knee balancer, such as one available from Sultzer, is used to gauge accuracy of ligament balance and used as fulcrum for elongation of the partial epicondylar osteotomy proximal attached soft tissues. The Sultzer balancer has a broad surface to decrease contact stress with the femur and tibia. It releases at a low maximum force that protects the cut surface of the tibia and femur from deformation. Continued distraction of the knee joint is applied until the desired lengthening is achieved. Fixation of the epicondylar osteotomy once the extension gap is balanced is important to avoid posterior migration of the epicondyle that would affect the flexion gap. If epicondylar posterior displacement occurs it will affect rotation of the femoral prosthesis resulting in altered tracking of the patella femoral joint.

With the knee in flexion, the drill guide penetrating blade **152** is positioned in the bone gap **110**. The knee is then moved to extension to check ligament tightness. If additional adjustments are needed further distraction can create additional effective length or slight closing of the gap can result in shortening. If the desired ligament length has been achieved then the bone block **112** can be fixed in the final position. In one aspect of bone block fixation **112**, the knee is extended while the guide **150** stays in place. The guide is palpated through the skin to locate the guide barrel **158**. An incision in skin S overlying the drill guide **150** is formed to access the guide barrel **158**. Once the desire position has been achieved, a drill can be passed through the drill guide to form an opening **164** in the bone block **112** and the femur F. As shown in FIG. **7**, a fastener **180** such as a screw can be threaded into the bone following opening **164** along axis L**5** to maintain the position of the bone block **112** relative to the femur F. Fixation preserves the effectively lengthening of ligament **102** which allows the knee joint to rotate slightly to a balanced position where the femoral component **113** of the trial is substantially parallel to the tibial component **115** as illustrated by angle A**1'** being substantially 0 degrees.

One sided exposure for fixation is an advantage however screw purchase of cancellous bone is problematic in osteoporotic patients and a screw without a washer can easily migrate thru the epicondyle. A washer (not shown) can be utilized with the screw depicted in FIG. **7**, but acts as a source to later weaken the ligament and also adds extra palpable material to a bony prominence. A special hook **196** (shown in FIG. **8**) has been designed to achieve fixation in a less prominent manner. It has the advantage of more contact with the ligament bone junction to increase the force necessary to pull through the osteotomy fragment. To place the hook, a tunnel is formed transversely through the femor and bone block, and a suture or cable **197** attached to the hook **196** is passed through the tunnel. The hook is attached to the bone block with attached ligament, the suture is tensioned and an anchor **198** engages the suture and the opposite side of the bone to maintain tension on the suture.

The balancing methodology has been described above for the varus knee because they are the most common knee deformity. The technique works equally well with valgus knees in which the lateral epicondyle is elevated with maintenance of the anterior periosteum. On the lateral side balancing of the contracted tissues begins with elevation of the contracted lateral capsule and IT band from the tibia. The posterior capsule is elevated from the posterior femur. Posterior femoral capsule attachment and even elevation of the lateral gastroc is aided by a limited osteotomy of the posterior lateral femoral condyle during extension gap balancing. Gradual distraction and fixation are performed the same as the medial side.

Another factor that can be considered when balancing a severely deformed knee is that part of the ligament inbalance is related to the attenuation and laxity of the opposite ligaments and capsule of the knee's less worn side. Dealing with this problem by over lengthening the worn side will negatively affect knee kinematics.

To address the laxity of the ligament, a method has been developed in which a cable or suture is placed to balance the knee once the shortened side has been returned to normal. This stabilizing cable or suture can also be used to affect laxity patterns that are identified when a laxity pattern becomes apparent during trialing or after the implant is secured. The technique involves placement of the stabilizing suture or cable in the epicondyle to impart a tension force in flexion, extension or both using the known center of the rotation of the specific prosthesis and point of laxity in flexion. Referring to FIGS. **9**A and **9**B, an elongated ligament tension element **206** is anchored to the femur at point **202** and to the tibia at point **204**. In flexion as shown in FIG. **9**A, the tension element **206** maintains a normal knee joint spacing **208** between the femur and tibia. Similarly, when properly positioned and tensioned, the tension element **206** also maintains a normal knee joint spacing **210** in extension as shown in FIG. **9**B. Circle **207** indicates a quadrant on the epicondyle for positioning of the tensioned ligament augmentation device to achieve the proper effect in both flexion and extension. With respect to FIG. **9**A, the preferred position may be more anterior and distal on the femur to achieve the proper tension in flexion. Conversely, as shown in FIG. **9**B, the position of fixation for the tensioned ligament augmentation device tends to be in a more posterior and proximal quadrant of the epicondyle for the proper effect in extension. The knee can be manipulated and observed to evaluate the proper positioning of the tension member on the femoral epicondyle.

Referring to FIG. **10**, the epicondylar anchor location is determined. In one form, the femoral condyle may be imaged or exposed for visual inspection and anatomical landmarks used to identify the proper position for anchoring of the ligament support member. In another form, a guide **230** secured to a femoral trial **220** or the implant itself may serve as an accurate means to identify the anchoring point to assure the stabilizing cable or suture is tensioned most at the lax segment of the flexion arc. The guide **230** includes an attachment portion **232** for releasably engaging the femoral trial **220** and an interconnected arm **233** that terminates in a guide tip **234**. When positioned in the knee, the guide tip will engage or point to a location on the bone for drilling. As shown in FIG. **10**, the guide tip may move slightly through a fixation area **236** as the knee is moved from flexion to extension. Attachment of the cable or suture should occur in the attachment area **236**, however there can be some modification within the zone to account for specific knee movements. For example, if a laxity in extension is noted after the trial is placed the epicondylar fixation point is going to be more posterior and proximal on the epicondyle. In contrast, if during deep flexion of the knee a portion of the ligament is particularly lax the epicondylar fixation point may be moved more anteriorly within the fixation are **236**.

Referring to FIG. **11**, the initial placement of a suture **140** in the knee is shown. A bone tunnel **144** is formed in the femur based on the anchor attachment point determined as explained above. The inferior portion of the elongated ligament tension element **140**, typically a suture or cable, is anchored to the tibia utilizing a bone anchor **142**. Anchoring in the tibia at the level of the prosthesis stem base with a suture or cable fixation aid that penetrates the cortex and then flips perpendicular to the cortex is a straight forward fixation method. In one form, the bone anchor **142** is an expandable anchor or flip anchor that can be delivered in a minimally invasive reduced size configuration and then expands after positioning in the bone to an enlarged anchoring configuration as shown in FIG. **11**. The ligament tension element **140** is positioned along lax ligament **104'** and the superior portion is positioned in bone tunnel **144**. Passing suture superficial to the deep MCL or lateral capsule but deep to the superficial MCL or lateral collateral is helpful. It is also beneficial to pass through the retinaculum to avoid impingement of the more superficial structures. In the illustrated embodiment, the suture is passed through the bone fragment attached to ligament **102'** and may be used as a fixation element to hold the bone fragment in position. However, in a preferred embodiment illustrated in FIG. **11**, the bone fragment is fixed separately and the bone tunnel **144** does not intersect the bone fragment.

Referring to FIG. **13**, although not limited to a specific design, additional details of a preferred elongated ligament tension element **140** are shown. The tension element **140** is formed of a polyester material in the form of a flattened strip or tape in the central area **170**. Example materials include the FiberTape® and TigerTape available from Arthrex which are flattened polyester sutures with an ultra-high molecular weight polyethylene core. Although widths may vary, in one form the tapes are 2 mm wide tapes. The tapes provide broad compression and increased tissue cut-through resistance compared to circular sutures. In addition to the use of suture tapes to limit pull through issues on bone tunnel **144**, or as an alternative thereto, a cylindrical bone protection ferrule (not shown) may be placed at the entrance to bone tunnel **144** to inhibit suture pull through on the opening. Such ferrules have a cylindrical body with a central passage to receive the suture and an enlarged head to engage the bone to inhibit migration. The transition between head and the opening in the cylindrical body is rounded or chamfered to inhibit abrasion of the suture. In the embodiment illustrated in FIG. **13**, the ligament tension member **140** is a composite of a polyester suture tape **170** and a metallic cable **181**. The tape **170** is joined to the cable **181** by a coupler **176**. The coupler has a series of openings **178** receiving a distal portion of the suture **174** and opening **180** sized to pass the cable while retaining portion **182** joined to the proximal end of the cable. It will be appreciated that the proximal end of suture **172** is joined to a movable anchor **142** for tibial fixation. The distal end of the cable **145** may be fixed to the bone in any of a variety of techniques know for cable to bone fixation.

Although it is contemplated that balancing of the knee can be accomplished by simultaneously adjusting both the tight ligament and the laxity on the opposing side of the knee, in practice, release of the tight ligament can be accomplished separately from tightening the laxity on the opposing side. Ligament tensioning is accomplished with an in-line tension device (not shown) attached to the cable end **145**. Use of a tension device, compared to manual pressure, allows more precise control of the tension force being applied. In addition, the tension device includes a force indicator measuring indicating the amount of force being applied to the cable **144**. In one aspect, the cable is tensioned to between 15 and 30 lbs of force. The knee is moved through one or more cycles through at least a part of the range of motion between flexion and extension while monitoring the force indicator. If forces above 30 lbs are indicated at any point along the range of motion, tension on the cable can be reduced by lengthening the ligament tension element **140**. Similarly, if tension on the cable falls below a lower threshold, such as 15 lbs, then the ligament tension element **140** can be shortened by the tension device to generate higher tension loads. It will be appreciated that the practice of adjusting the tension can be repeated as many times a necessary before committing to a cable or suture length. This method also allows cycling of the knee to draw any creep from the suture before the anchor is secured. In one preferred aspect, the target tension on the cable end **145** in the positions shown in FIGS. **9**A and **9**B is approximately 25 lbs of force.

As shown in FIG. **12**, the ligament tension element **140** may be tensioned to achieve the desired knee balance such that femur condyle surface **160** of the upper knee replacement component is maintained in close approximation or contact with the tibial component surface **162**. In comparing FIG. **11** to FIG. **12**, the gap between these two surfaces is reduced by the application of tension to tension element **140** and the knee joint is more closely aligned from the unbalanced knee of FIG. **11** to a balanced position as shown in FIG. **12**. Once the desired alignment and ligament balance has been achieved, tension on the ligament tension element **140** is maintained by securing the distal segment **145** to the distal portion of the femur. In one form, an expandable anchor **146** is secured to the distal segment **145** and then moved to an anchoring configuration to maintain the position. In another form, an enlarged member such as a washer is slid down the distal segment to engage the bone and a ferrule is crimped to the distal end **145** to maintain the position of the cable relative to washer and thereby maintain force against the bone. As discussed above, the location of the suture **140** tunnel **144** through the femur is based on the center of rotation of the prosthesis as determined by a femoral trial positioned in the joint or by the actual prosthesis. Thus, the function of the knee can be optimized by properly tensioning the ligaments. Also, if fine tuning adjustments need to be made after final placement of the prosthesis (both during the initial surgery or in a follow-up procedure), the suture **140** can be loosened or tensioned as needed to achieve the desired correction of ligaments **102'** or **104'**, or both.

In another aspect of the present disclosure, a system **400** shown in FIGS. **14-17** is provided to enhance equalization of the flexion and extension gap. As will be explained in more detail below, the system **400** utilizes a pair of fluid filled bellows **420** and **440** to permit a virtually infinite number of positions or heights to more accurately assess and maintain the proper flexion and extension gap in the knee during preparation of the bone for receipt of an implant as well as balancing knee ligament tensions.

The extension gap for knee replacement procedures is determined by bone cuts of the femur and tibia. Cuts are made based on standing full length pre-op x-rays and may be refined based on data bank of knee alignment and progression of disease. Bone cuts are made to restore mechanical axis to 0 degrees or within 2 degrees of neutral mechanical axis, but the varus knee stays in up to 2 degrees of varus and any shift in valgus is avoided.

Currently the mechanical axis is checked by C-Arm, but navigation is another alternative. Once cuts are made and checked the extension gap is made rectangular by ligament releases. Rectangular gap shape and millimeters of gap height are currently measured by a ratcheted balancing device. The ratcheted devices have a disadvantage in recording displacement and torque accurately. Ratcheted devices utilized have large (1.5 mm or 2 mm increment measured) of displacement and are somewhat difficult to read. There is often a large jump in force required to achieve the closest ratchet elevation needed to appropriately tension the ligaments. Therefore some discrepancies in gap balancing are inherent.

The other problem is that the current ratcheted balancers cannot be used as cutting guides or guides for cutting block pins. Therefore they are useful only as a device to check gap equalization which is not efficient and requires multiple cuts in most situations. Deviations in flexion and extension gaps therefore can be at least 2 millimeters even when trying to be as accurate as possible. Gap balancing is also more accurate when the patella is anterior which is impossible with distractors that are not disassembled.

A bellows apparatus **400** has been designed to allow accurate assessment of pressure and displacement. The extension gap is measured which allows exact replication when completing the flexion gap. The bellows are fluid filled and the fluid pressure as well as displacement is measured. Referring to FIG. **14**A, a top view is shown with the upper plate **412** illustrated with the inflation lumens **416** and **418** extending outwardly beyond the perimeter of the upper plate. In FIG. **14**B, a bottom view shows the lower plate **414** with the inflation lumens **416** and **418** extending outwardly beyond the perimeter of the bottom plate. As illustrated, both inflation lumens extend from the same side of the bellows assembly **410**. FIG. **15**A is a cross section of FIG. **14**A taken along line A-A. Bellows **420** include corrugated sidewalls. In one form, the sidewalls include a series of rings **421** joined by a flexible material forming a fluid tight chamber **430** that can expand longitudinally along axis L**4**, but is constrained by the rings from expanding radially outwardly. In an alternative form, the sidewalls of the bellows are formed of a relatively stiff material that does not distend under pressure but because of the folds **423** may expand longitudinally along the axis L**4**. A central post **422** helps to maintain alignment as the bellows expand in the direction E from a first height H**1** to a second larger height. Referring now to FIG. **15**B, this is a cross-section taken along line B-B of FIG. **14**A. This view shows bellows **440** along with the fill aperture **419** that is connected to inflation lumen **416** that are used to inflate fluid tight chamber **450**. Bellows **420** and **440** are constructed in the same manner.

Referring to FIG. **16**, the bellows balancing system **410** is shown interconnected with the filling tubes **480** and **482**. The filling tubes **480** and **482** are connected to pumps **484** and **486**, respectively. It will be appreciated that movement of handles **488** and **490** via rotation will generate fluid pressure in the system that can be displayed by pressure gauge **492** and **494**, respectively. Each of the bellows is inflated independently permitting precise changes in angles and pressures to achieve the proper balance of the knee joint. Typically the bellows are utilized before cuts are made so the bellows provides a guide for the proper amount of bone removal needed to proper fit the knee replacement implant. Referring to FIG. **17**, the bellows balancing system **410** is placed in the knee joint before expansion and then expanded in situ until the desired height and/or pressure is achieved.

If a subtle difference exists in extension gap symmetry, it can be identified by the bellows. Modification of the femoral cut can be used by securing a cutting guide based on the platform of the bellows apparatus **410**. The refinement in the bone cut is made only if the mechanical axis following the correction is felt to be acceptable. In this manner a perfect symmetrical extension gap is accomplished to allow easy duplication in flexion. Factors such as limb position, limb support, tibia rotation, patella position, optimal ligament cycling and tension response and effect of PCL partial release can be studied accurately.

Additional details of the bellows apparatus **400** is set forth in FIGS. **16** and **17**. As described above, each syringe can provide a range of expansion force up to 25 lbs., although additional force up to about 40 lbs. could be generated by larger syringes if desired. Further, although dual bellows are disclosed in the present embodiment to provide greater variability between lateral aspects of the knee, it is contemplated that a single bellows can be provided to achieve desired gap refinement. Also, an index (ruler) may be attached to the anterior surface of the bellows to provide a measurement off the bellows to allow the drilling of holes for placement of jigs to guide making cuts in the bone.

The above devices and methods have been described in the context of an open surgical technique that is manually implemented. It is contemplated that one or more aspects of the technique can be implemented by a robotic surgical system configured for knee surgeries such as that described in US2009/0000626 entitled "Haptic Guidance System and Method," incorporated herein by reference in its entirety.

The foregoing outlines features of several embodiments so that those skilled in the art may better understand the aspects of the present disclosure. Those skilled in the art should appreciate that they may readily use the present disclosure as a basis for designing or modifying other processes and structures for carrying out the same purposes and/or achieving the same advantages of the embodiments introduced herein. Those skilled in the art should also realize that such equivalent constructions do not depart from the spirit and scope of the present disclosure, and that they may make various changes, substitutions and alterations herein without departing from the spirit and scope of the present disclosure. Furthermore, although elements of the described embodiments may be described or claimed in the singular, the plural is contemplated unless limitation to the singular is explicitly stated. Additionally, all or a portion of any aspect and/or embodiment may be utilized with all or a portion of any other aspect and/or embodiment.

What is claimed is:

1. A method for load balancing in knee replacement procedures, the method comprising:

evaluating ligament balance in a knee;

loosening a first over tight ligament on a first side of the knee by performing a partial epicondylar osteotomy adjacent a bone/ligament attachment point of the first ligament by severing a superior portion of the bone adjacent the bone/ligament attachment point while leaving an inferior portion of the bone adjacent the bone/ligament attachment point connected to the native epicondylar bone to thereby form a bone flap positioned over a bone defect;

adjusting the tension on the first ligament by effectively lengthening the first ligament by moving the bone/ligament attachment point on the bone flap inferiorly toward the foot; and

fixing the bone flap with interconnected bone/ligament attachment point to the epicondyle to maintain the position of the bone flap relative to the epicondyle to thereby fix the new effective length of the first ligament.

2. The method of claim 1, further including:

inserting a penetrating blade of a drill guide in the bone defect beneath the bone flap;

moving the knee from a flexion position to an extension position with the drill guide positioned in the bone defect;

using the drill guide to form at least one opening in the bone flap; and

positioning a fixation element in the opening in the bone flap to thereby fix the position of the bone flap.

3. The method of claim 1, further including:

identifying a loose ligament that is too lax to properly function to support the knee after insertion of a knee replacement device;

anchoring an end portion of an elongate ligament support member below the knee;

extending the elongate ligament support member along the loose ligament;

evaluating tension of the elongate ligament support member in at least one of flexion and extension of the knee;

determining appropriate tension on the elongate ligament support member; and

fixing a superior portion of the elongate ligament support member to the femur to maintain the appropriate tension.

4. The method of claim 2, wherein the inserting a penetrating blade includes orienting the penetrating blade such that an aperture extending therethrough extends in the medial to lateral orientation when the penetrating blade is positioned in an epicondylar osteotomy, and wherein the drill guide is joined to the penetrating blade by a support arm, the drill guide including a passage with a guide axis, the support arm aligning the guide axis with the aperture.

5. The method of claim 4, wherein the using the drill guide includes spacing a proximal end of the drill guide outside of soft tissue overlying the epicondylar osteotomy when the knee is in extension, wherein the support arm has a length sufficient between the penetrating blade and the drill guide for the spacing.

6. The method of claim 2, wherein the loosening a first over tight ligament includes forming the osteotomy using an epicondylar osteotomy saw blade, the saw blade having a width and a thickness and wherein the penetrating blade has a blade width and a blade thickness substantially matching the saw blade width and thickness.

7. The method of claim 2, further comprising maintaining the penetrating blade in the correct position using a retention means of the penetrating blade for engaging the bone inside the osteotomy.

8. The method of claim 2, wherein the positioning the fixation element includes engaging a hook to an epicondylar osteotomy bone flap.

9. The method of claim 8, wherein the engaging a hook includes extending the flexible elongate element coupled to the hook through a bone tunnel in the femur.

10. The method of claim 9, wherein the engaging a hook includes securing a bone anchor coupled to the flexible elongate element on an opposite side of the femur including the hook.

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